

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-02				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2020 Base Option Period Number 1			Title of Work Assignment/SF Site Name				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW RRP Lead Outreach					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance From 06/13/2017 To 06/12/2018					
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2016 To 06/12/2020										
This Action: 										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Darlene Leonard <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-0516 FAX Number:			
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

Contract Number: EP-W-16-017

Work Assignment Number: 1-02

Change Number: 0

Title: RRP Lead Outreach

I. Purpose and Background

This work assignment is a continuation of WA 0-02 under Contract EP-W-16-017. This Work Assignment continues and expands upon the work initiated in WA 0-02 under Contract EP-W-16-017 and provides technical support for the implementation of the Renovation, Repair and Painting Program as well as all other aspects of the Lead-Based Paint Program. No work shall be repeated that was previously completed in WA 0-02.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. Specifically Section 405 (a) says “ The Administrator, in cooperation with other appropriate Federal departments and agencies, shall conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection and abatement of lead-based paint and other lead exposure hazards” Section 405 (d) says “the Administrator in conjunction with the Secretary of Health and Human Services...and in conjunction with the Secretary of Housing and Urban development, shall sponsor public education and outreach activities to increase public awareness...”

Throughout the year, EPA provides lead awareness and educational outreach to various audiences. In addition, EPA partners with the Centers for Disease Control and Prevention (CDC) and the Department of Housing and Urban Development (HUD) to collaborate on a theme and develop posters and flyers and other education and awareness tools and events specifically designed to observe National Lead Poisoning Prevention Week (NLPPW). EPA also promotes the Lead Week of Action, a lead awareness effort on an international scale.

II. Scope of Work

Task 5 General Lead Outreach

The Contractor shall:

- Provide technical support for general lead outreach, including finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, developing outreach presentations, support for developing, shipping and staffing conference exhibit booths and meetings, translation of existing EPA documents into additional languages, and outreach support involving Historically Black Colleges and Universities (HBCUs) as directed by the EPA WAM.

III. Deliverables:

- Summary of Work
The Contractor shall provide a letter report providing statistics on the activity for the contract period.
- Graphic Files and Support
The Contractor shall provide graphic print files for documents (pamphlets, posters,

banners, flyers, social media postings, and other tools) and support for other outreach events and activities, as directed by the EPA WAM.

A work plan is required.

A Quality Assurance Project Plan is not required since no data collection applies.

CBI does not apply.

This work assignment relates to Tasks III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:

This work assignment will start on the date of the Contracting Officer signature and extend through June 12, 2018.

V. Estimated Level of Effort: 80 professional hours

VI. EPA Contacts:

Work Assignment Manager:

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Deputy Work Assignment Manager:

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Phone: 202-564-8834

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-03				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2020 Base Option Period Number 1			Title of Work Assignment/SF Site Name PCB/Disposal Cleanup				
Contractor BATTELLE MEMORIAL INSTITUTE						Specify Section and paragraph of Contract SOW				
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Work Assignment Manager Name Gail Hansen <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-308-0463 FAX Number:			
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
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Work Assignment Form. (WebForms v1.0)

STATISTICAL & TECHNICAL SUPPORT FOR THE ASSESSMENT OF TOXIC SUBSTANCES

BACKGROUND

The Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics (OPPT) of the Office of Chemical Safety and Pollution Prevention Washington, D.C., under the auspices of the Toxic Substances Control Act (TSCA), (Sections 4, 5, 6 and 8 (Title IV) and Goal 4 - of the OPPT Mission; Healthy Communities and Ecosystems; Sub-objective 4.1.1: Reduce Chemical Risks; has the responsibility to collect data for chemical assessments and to support the regulatory and pollution prevention activities of the Office. These studies relate to organic and inorganic substances under the jurisdiction of TSCA.

OBJECTIVE

The purpose of this procurement is to provide statistical, mathematical, field data collection, and technical analysis support and planning for OPPT programs. This capability is needed to identify long and short term program objectives, develop well formulated data collection programs, provide the means to track progress made toward meeting stated program objectives and to conduct those statistical, technical and scientific studies that will provide for technically feasible, fiscally sound and effective programs. OPPT also provides support for programs in the areas of economics, chemistry, engineering, and exposure assessment. OPPT's economic analysis supports rulemaking and helps the Agency determine promising non-regulatory approaches. OPPT also manages the Risk -Screening Environmental Indicators Model, which provides information on the relative risk impacts of chemical releases from industrial facilities, and leads the Design for the Environment and Green Chemistry Programs, which focus on voluntary pollution prevention.

The work performed under this solicitation will include EPA's lead-based paint (LBP) program, which has a goal of eliminating childhood lead poisoning as a major public health concern. The LBP program provides technical and program development assistance to the U.S. Department of Housing and Urban Development (HUD) in the areas of detection, measurement, and abatement/management of lead-based paint hazards in housing. This support was formalized in a Memorandum of Understanding between EPA and HUD signed in the spring of 1989. The Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X) gives EPA a strong role in addressing the national problems of lead-based paint in housing and the broader problem of childhood lead poisoning. EPA's lead strategy recognizes lead-based paint in housing as an important contributor to elevated blood lead levels in children. More specific program goals and objectives will be identified in work assignments.

EPA's budget and individual projects are tied to the Government Performance and Results Act (GPRA) goals. The agency is required to report to the Congress on its progress towards meeting those goals. This procurement may be used to evaluate EPA's progress under specific GPRA goals.

SCOPE OF WORK

The contractor shall develop reasonable and cost-effective approaches to accomplish the objectives of each work assignment. Various financial and time constraints specified in work assignments will limit the extent of any project and the contractor shall deliver optimum value in light of these constraints. As

specified in work assignments, the contractor shall develop the required data in a format (specifications to be provided in work assignments or by written technical direction) which is compatible and consistent with existing data and databases. The contractor shall comply with the agency's Quality Program Policy Standards and Procedures, per EPA Orders CIO 2106.0 and CIO 2105.0 in the performance of the work under this contract. During performance of the contract, the contractor shall immediately inform the Project Officer by telephone and in writing of any problems that impede performance, suggest corrective actions necessary to solve the problems, and implement these actions as specified by the contracting officer.

The contractor shall perform tasks, as specified by work assignments, in the following five areas: (1) Collection of Data; (2) Analysis of Data; (3) Technical Program Support- General; (4) Technical Support-Specific and (5) Physical Testing. All activities will be accomplished using level of effort contracting and performance-based contracting.

The contractor is required to comply with all Section 508 requirements in work areas that are held to such requirements under EPA Order 2100.

All contractor, subcontractor, and consultant personnel shall wear prominently displayed identification badges at all times when performing tasks under this contract when interaction with EPA officials, federal agencies, state, tribal and local governments, businesses, industry and the general public. The badge shall contain the individuals name and the company's name and logo. When participating in any event, meeting or discussion, contractor staff shall verbally identify themselves as contractor personnel, so that there is not a possible appearance of being EPA officials.

The contractor shall submit all analyses, options, recommendations, reports and training materials required under this contract in draft for critical review by the contracting officer or contracting officer's representative (COR). The Government will make all final regulatory, policy and interpretive decisions resulting from contractor-provided recommendations. The contractor shall not publish or otherwise release, distribute or disclose any work product generated under this contract without obtaining EPA's express written approval. When submitting materials or reports that contain recommendations, the contract shall: explain or rank policy or action alternatives, describe procedures used to arrive at recommendations, summarize the substance of deliberations, report any dissenting views, list the sources relied upon, and detail the methods and considerations upon which the recommendations are based.

The contractor shall prepare a Quality Assurance Project Plan (QAPP) and obtain EPA approval of the QAPP before the conduct of environmental data activities.

DELINEATION OF TASKS

Task I. Collection of Data

1. Develop and implement statistically-valid experimental and survey designs for field monitoring, laboratory studies or other data collection efforts, including the design of data collection forms. A particular study to be performed by the contractor may involve one or more environmental media and the detection and quantification of residue levels of one or more chemicals. The contractor shall determine probable biases and sources of error due to sampling and analytical methods employed and recommend design and/or analysis modifications to minimize error. The contractor shall recommend the proper sample collection program. The contractor shall assess the method of sample collection and the chemical analytical procedure in the design of collection routine. The contractor shall evaluate the basic design

issues concerning the method of specimen collection, time period of collection, and duration of the collection effort to ensure statistically-valid and reproducible results.

2. As specified in individual work assignments, the contractor shall:

a. Develop the statistical design for a national or local probability survey where data collection involves the gathering of information, such as information on consumer habits or the work practices of various subgroups exposed to a particular chemical or group of chemicals. The contractor shall develop a sampling frame using available resources to target and access the desired population. The survey developed by the contractor may use telephone or mail procedures for data collection and the contractor shall design and test a questionnaire for obtaining the necessary information.

b. Collect and/or measure environmental and biological samples and administer questionnaires and perform visual inspections or visual assessments, and provide appropriate training for personnel who perform such tasks.

c. Prepare sufficient documentation for administering a questionnaire or similar device to persons participating in a data collection effort. The documentation prepared by the contractor shall adhere to OMB approval requirements, and shall comply with OPPT objectives as specified in work assignments.

d. Perform probabilistic modeling to test proposed sampling protocols in order to optimize study design.

e. Provide expertise and perform tasks related to preparation of information collection packages under the Paperwork Reduction Act for purposes of EPA obtaining Office of Management and Budget (OMB) approval for data collection activities. The contractor shall perform in accordance with EPA Guidance on completing information collection packages.

f. Provide expert technical or peer review of statistical studies, including review and comment upon various monitoring protocols and studies.

g. Develop statistically-valid options for study and experimental design including sample size, schedule and cost options. The contractor shall include the pros and cons for each option.

h. Develop and implement results and performance evaluation studies, to evaluate federal, state, or local government programs, regulations, and guidance. This includes the development of plans, designs, objectives, sampling frames, questionnaires, and other survey instruments. This also includes training survey staff with appropriate training materials, contacting survey participants and administering questionnaires and collecting samples as necessary.

Task II. Data Analysis

1. The contractor shall provide the statistical and other technical expertise necessary to support ongoing OPPT programs including: analyzing data, interpreting results, writing reports for publication, providing briefing materials and carrying out briefings on status and results, performing all necessary quality assurance, (including validation) studies, conducting pilot studies as necessary prior to implementation of full studies, and tracking the status of the studies.

2. The contractor shall perform the following tasks: determine the reliability of the data; extrapolate results for exposure assessment studies and exposure projections, conduct model development validation

and prediction verifications from previous studies, and apply the data to programs other than the program which initiated the specimen collection and chemical analysis effort as needed.

3. The contractor shall process and analyze existing data sets containing data from previously conducted monitoring studies. The contractor shall interpret existing data in light of EPA information needs and objectives as specified in work assignments and present results in both statistical and non-statistical language. In addition, the contractor shall develop and maintain databases resulting from monitoring and field studies, as well as those data collected via other means, and provide documentation of the databases.

4. The contractor shall: utilize state-of-the-art statistical methodology, such as pattern recognition techniques or measurement error analyses, where appropriate, to analyze data collected by the contractor or to analyze data furnished by EPA; analyze data using appropriate statistical techniques commensurate with the way the data was collected; provide documentation of data sources and data description, and documentation of analysis techniques and methods; conduct simulation studies and perform mathematical or probabilistic modeling to test proposed sampling and data collection protocols in order to evaluate the efficiency of the study design; write reports on data analysis for publication and develop and maintain databases resulting from monitoring and field studies, as well as those data collected via other means, and provide required documentation.

5. The contractor shall provide statistical and analytical quality assurance expertise and perform tasks necessary to support OPPT, and the National Program Chemicals Division. Specifically, the contractor shall support the exposure assessment activities through the collection and analysis of new and existing data, and provide an assessment of their applicability to Agency needs. The contractor shall perform the following tasks: a) determine the quality and reliability of the data; b) extrapolate results for exposure assessment studies and exposure projections; c) conduct model development, validation and prediction activities from previously existing studies; and d) apply the data to other programs as necessary.

6. The contractor shall conduct statistical analysis of chemical assessment data, quantitative risk assessments (QRAs), hazard assessments, and epidemiological studies and reviews.

Task III. Technical Program Support - General Support

1. Provide literature searches of technical studies on technical or scientific topics and provide lists and/or summaries of the studies obtained through the literature search.

2. Provide technical review or peer review of statistical, biostatistical, epidemiologic and other technical studies, or portions of those studies. This includes review of plans, designs, protocols, statistical and chemical analysis methods, questionnaires, data analyses, draft and published reports, brochures, pamphlets, and journal or book articles.

3. Develop guidelines and fact sheets for dissemination to both professionals and to the general public. Conduct focus groups or other review mechanisms by the intended users of the guidelines or fact sheets to obtain feedback and reaction prior to publication.

4. Provide data and accompanying documentation in appropriate paper and computer file formats that can be released to EPA, other federal and state agencies, and to the general public. The format of the data can vary from ASCII files, to Word files, to SAS files.

5. Use or develop statistical analysis and economic/risk assessment procedures to evaluate competing technologies on the basis of their cost effectiveness, their effectiveness toward meeting program objectives and the technological risks associated with the program's likelihood of success.

6. Plan, design, and implement public seminars or workshops both nationally and internationally on technical issues at which recognized experts would have the opportunity to present state-of-the-art methodologies, results, and emerging issues.
7. Develop and present technical training sessions for EPA staff in statistics, chemistry, biology, epidemiology, and computer science.
8. Develop products or deliverables required under this contract utilizing available technological approaches for information dissemination that are appropriate to the subject matter involved. Existing techniques, information formats and information dissemination approaches can include, but are not limited to: Compact Disc, Video and Audio Recordings, Internet accessible information files, Color graphics, and Local and Wide Area Networks. The use of these technologies shall be identified in the work plan and approved by the work assignment manager.
9. Provide briefing and presentation materials on the analyses and projects conducted under this contract. Conduct briefings when requested on the analyses and projects conducted under this contract.
10. Complete reports for EPA publication on the projects conducted under this contract. This includes responding to all technical and editorial comments on the draft reports so as to produce a final report that meets EPA criteria and standards for publication, developing and producing report cover designs consistent with EPA standards, submitting camera-ready copies of the report and cover design for submission to the EPA print shop, and, if requested in the work assignment, a version of the report suitable for inclusion on an Internet Web Page.
11. As specified in work assignments, coordinate and conduct meetings and briefings at which the contractor shall present results of the research and analyzes performed under this contract. The contractor shall present technical papers at conferences. The contractor shall also conduct focus groups and stakeholder meetings with the objective of obtaining feedback and reaction from interested parties regarding technical products and planning.
12. Develop publication formats using state-of-the-art technology, such as videos, CD-ROMs, computer diskettes, Internet-accessible files, illustrated brochures, and presentation slides, overheads, and graphics to make technical reports, guidelines, fact sheets, and other products available to the widest possible audience.
13. Where required, provide logistical support for technical meetings. This support includes, but is not limited to, providing meeting space when Government space is not available; court reporter services; appropriate meeting presentation equipment; preparation of agendas; meetings information to participants; and proceedings of the meeting.
14. Develop strategy documents for responding to health, environmental, and related issues.
15. Develop technical guidelines and provide support for the development of regulations for TSCA chemicals.

Task IV. Technical Program Support - Program Specific

1. Conduct technical studies on a variety of TSCA program issues. The contractor shall evaluate new and emerging technologies to assess their impact on meeting the objectives of the TSCA program.

2. Evaluate current and proposed technology to measure, detect, or reduce exposure to toxic substances, including lead, mercury, polychlorinated biphenyls, and other chemicals of concern under TSCA.
3. Support programs that evaluate the risks of classes of chemicals by maintaining program information, tracking progress of program chemicals, evaluating correspondence and test plans, providing robust summary submissions and updating the web site as well as analyzing program status.
4. Provide support to the Lead Renovation, Repair, and Painting regulation for Public and Commercial Buildings. This may include research on work practices and maintenance procedures.
5. Provide support to the Mercury Program in the areas of addressing mercury releases, addressing mercury uses in products and processes, managing commodity-grade mercury supplies, communicating to the public about mercury exposure risks, addressing international mercury sources and conducting mercury research.
6. Provide risk exposure assessments relating to PCBs and other potential environmental contaminants such as Mercury and Dioxins. These assessments are performed using easily available information from the open literature, EPA files or other sources and require experience in conducting environmental chemical/compound (PCBs, Dioxins, Mercury) risk investigations. Specifically, this element includes, but is not limited to: (1) maintaining PCB Transformer Registration spreadsheets; (2) developing and formatting outreach materials for chemicals of interest; (3) conducting peer reviews of technical guidance, and (4) conducting market surveys.
7. The contractor shall provide support to EPA's Existing Chemicals Program which addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high hazard and risk, EPA will choose from among many actions that it is authorized to take under the Toxic Substances Control Act. The Agency may pursue such regulatory actions as restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers. Specifically the contractor shall assist EPA with managing chemical data under its Chemical Data Reporting (CDR). Work may include supporting Internet communications, preparing webinar and training modules, and producing outreach materials. EPA may ask for help in querying CDR information, and may also require assistance in querying previous chemical data reporting cycles related to the Inventory Update Reporting (IUR) periods of 2006 and earlier. EPA may request CDR/IUR statistics in terms of chemical production volume, companies, industrial processing and use, consumer and commercial use, and other related information.

Task V: Physical Testing

1. The contractor shall apply Quality Assurance (QA) methodology and guidelines, including Quality Assurance Project Plans (QAPPs) and Data Quality Objectives (DQOs), to all physical testing requirements specified in the individual work assignments. Because of the complexity and variety of these requirements, the performance objectives, and performance standards will be defined at the work assignment level. A Quality Assurance Plan (QAPP) shall be submitted by the contractor in accordance with the schedule for each work assignment. Testing will not commence until the EPA Quality Assurance Manager has approved the QAPP. The QAPP shall be the primary evaluative tool for the Project Office when determining successful performance.

2. The contractor shall perform laboratory analysis of environmental and biological samples for the full range of the Office of Chemical Safety and Pollution Prevention chemicals. All testing shall be performed in accordance with the approved QAPP. These tests and analysis include, but are not limited to, inorganic compounds such as lead, mercury and other heavy metals; Persistent, Bioaccumulative and Toxic chemicals such as mercury, cadmium and lead; organic compounds such as dioxin, furans and PCBs; endocrine disruptors such as estrogen and androgens; Voluntary Children's Chemical Evaluation Program chemicals such as perfluorooctanoic acid (PFOA) and vinylidene chloride; isotopic analysis of compounds such as lead oxide to determine the source of the element or compound; geochemical reactions such as mercury methylation in sulfur cycling; microbial agents and biochemical reactions ; and blood, hair, urine and various types of tissue samples from both humans and animals. This shall be accomplished using state-of-the-art quality control and quality assurance mechanisms to ensure the validity of the laboratory results. Frequently, the analyses will require analytical methods that are commonly available in commercial laboratories.

3. QAPPs shall include the following information: problem definition; quality objectives and criteria for measurement data; experimental design; analytical methods; quality control; data management; assessment/oversight; data review, validation and verification; verification and validation methods; and reconciliation with user objectives. Specific QAPP requirement will be specified in the individuals work assignments.

PERFORMANCE MEASURES

Task I. Collection of Data

Once a year (during each contract period of performance) the Government shall review the promptness of submitting a final report as required in the work assignment. If the contractor is late more than 14 calendar days, from the due date as specified in the work assignment, the Government shall take a 10% reduction in the fee associated in that Work Assignment. The reduction will be applied to both the paid fee and unpaid fee for that work assignment.

Once a year (during each contract period of performance), the Government shall review the completeness of the report as required in work assignment. If the contractor's report is incomplete, the Government shall take a 10% reduction in the fee related to the delivered LOE in that work assignment. The reduction will be applied to both the paid fee and unpaid fee for that work assignment.

Task II. Data Analysis

Once a year (during each contract period of performance), the Government shall review the promptness of submitting the final report as required in work assignment. If the contractor is late more than 14 calendar days, from the due date as specified in the work assignment, the Government shall take a 10% reduction in the fee related to the delivered LOE in that work assignment. The reduction will be applied to both the paid fee and unpaid fee for that work assignments.

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Task III. Technical Program Support - General Support

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Task IV. Technical Program Support - Program Specific

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Task V: Physical Testing

Once a year (during each contract period of performance), the Government shall review the promptness of submitting the QAP's as required in the work assignment. If the contractor is late more than 14 calendar days, from the due date as specified in the work assignment, the Government shall take a 10% reduction in the fee related to the delivered LOE in that work assignment. The reduction will be applied to both the paid fee and unpaid fee for that work assignment.

Once a year (during each contract period of performance), the Government shall review the completeness of the submitted QAPP's as required in work assignment. If the contractor's QAPP is missing one or more of the required elements as listed in number 3 above, the Government shall take a 10% reduction in the fee related to the delivered LOE in that work assignment. The reduction will be applied to both the paid fee and unpaid fee for that work assignment.

Once a year (during each contract period of performance), the Government shall review the results of the physical testing as required in work assignment. If the contractor has failed to perform the physical testing in accordance with the approved QAPP the Government shall take a 30% reduction in the fee related to the delivered LOE in that work assignment. The reduction will be applied to both the paid fee and unpaid fee for that work assignment.

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Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
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Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Robert Courtnage <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-1081 FAX Number:			
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-04				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2017 To 06/12/2018			Title of Work Assignment/SF Site Name				
			Base Option Period Number 1			Formaldehyde				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance From 06/13/2017 To 06/12/2018					
Comments: The purpose of this Amendment is to add 70 hours to the LOE. The Contractor submit a work plan within 30 days of receipt of the work assignment amendment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2017 To 06/12/2018										
This Action: 										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Robert Courtnage <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-1081 FAX Number:			
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

Contract Number: EP-W-16-017

Work Assignment Number: 1-04

Change Number: 0

Title: Support for Formaldehyde Compliance Guides and Other Outreach

I. Purpose and Background

To provide EPA technical support to develop guidance materials for the Formaldehyde Emission Standards for Composite Wood Products regulations. This project is a continuation of work assignment (WA) 0-04 under contract EP-W-16-017. This WA continues the work initiated in WA 0-04 under contract EP-W-16-017. No work shall be duplicated.

Title VI of the Toxic Substances Control Act (TSCA Title VI) establishes formaldehyde emissions for composite wood products and requires EPA to promulgate regulations to ensure compliance with these emission standards. EPA has promulgated regulations for TSCA Title VI which have requirements for manufacturers (including importers), fabricators and laminators of composite wood products. Other entities, such as retailers, wholesalers, and distributors are required to sell, supply, or offer for sale, only composite wood products that are compliant with the regulations. The regulations also establish a third-party certification program for composite wood products. The contractor shall translate and revise, as needed, small entity compliance guides, as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and other rule compliance-related materials as directed by the work assignment manager (WAM). The contractor shall provide, as directed by the WAM, technical and graphical support for final rule implementation outreach including materials for the EPA Formaldehyde Resource Directory (website).

II. Scope of Work:

Task 1: Develop a Work Plan

The contractor shall prepare and submit a work plan in accordance with the contract requirements.

Task 2: Language Translations of Small Entity Compliance Guides

For each of the final English language Compliance Guides including: 1) third-party certifiers and accreditation bodies, 2) panel producers, 3) importers, distributors and retailers, and 4) fabricators (including laminators), provide up to 3 language translations, as needed and as directed by the WAM. The final Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: EPA Formaldehyde Resource Directory (website) Technical Support

The contractor shall provide support, as directed by the WAM, for technical and graphical materials related to the Formaldehyde Emission Standards from Composite Wood Products final rule implementation and compliance including materials for the EPA Formaldehyde website.

III. Deliverables:

Task 1: Work plan submitted within 30 working days of receipt of work assignment.

Task 2: The contractor shall provide the WAM written translations, in a language directed by the WAM, of the four English language Compliance Guides within 35 working days after being tasked by the WAM. The files shall be professional print-ready files and suitable for EPA web publication. The final translated Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: As directed by the WAM provide graphics, displays, forms, etc., for print or for the EPA Formaldehyde website.

A work plan is required.

A QA/QC plan is not required since no data collection applies.

CBI does not apply.

This work assignment relates to Tasks III, and IV of the current Statement of Work (SOW) of the contract. The work assignment shall start upon the Contracting Officer's signature and extend to June 12, 2018.

Estimated Level of Effort: 180 hours

WAM Contact Information:

Robert Courtnage
courtnage.robert@epa.gov
202-566-1081

Deputy WAM Contact Information:

Todd Coleman
Coleman.todd@epa.gov
202-564-1208

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-05				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name Statistical Supp Clean Water				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2018										
This Action:						1				
Total:						1				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name Brian Schnitker <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-0838 FAX Number:				
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				

Contract No. EP-W-16-017
Work Assignment 1-05

TITLE: Statistical Support for Clean Water Act

This new work assignment relates to Task I Collection of Data, Task II Data Analysis, and to a lesser extent, Task III Technical Program Support - General Support, of the current Statement of Work (SOW) of the contract. In particular, the work assignment will provide support for activities authorized by the Clean Water Act. The contractor shall provide support in areas including statistical analysis of laboratory data, statistical review and comment, and statistical documentation. A work plan is required (see Task 1).

This Work Assignment will provide follow-on statistical support for the NY/NJ Harbor and Super Storm Sandy Study (Task 10 in WA 4-4 under Contract EP-W-09-024) and monitoring support (Task 13 in WA 4-4). The WA also will provide statistical support for designing a survey of POTWs (i.e., a new project). The WA's tasks do not duplicate statistical support previously tasked elsewhere. EPA will not provide any data/information that are Confidential Business Information (CBI) for use in the work assignment.

I. BACKGROUND

A. NY/NJ Harbor Statistical Analyses (Task 3)

EPA plans for the work to be completed by **August 30, 2017**. This deadline applies to Task 3 only, not the entire work assignment.

For its assessment of post-SSS conditions in the summer of 2013, EPA-Region 2 collected samples from sites selected from the previous 2008 REMAP probability-based sampling design. Starting on October 28, 2012, Super Storm Sandy (SSS) arrived offshore of NY and NJ with hurricane force winds, heavy rainfall, and a tidal surge that damaged or destroyed approximately 500,000 homes and businesses, caused breaches in the barrier islands, and inundated Superfund sites and wastewater treatment facilities. Resultant flooding, as well as sustained power outages, released and/or redistributed contaminants. The NY/NJ Harbor complex (Upper Harbor, Lower Harbor, Newark Bay and Jamaica Bay), as well as Barnegat Bay in NJ, and freshwater tributaries along the coast were the USEPA-Region 2 water resources that were particularly impacted.

Using EPA's consolidated database, the contractor shall use the data from the 1993/4, 1998, 2003, 2008 and 2013 Harbor samples and the freshwater biological sampling results to statistically compare and assess pre- to post-SSS sediment conditions and any trends that may be present. None of the data are CBI.

It should be noted that much of this task has been completed and EPA does not expect a significant amount of work to be performed on this task. Time should be allotted, however, to address any issues or refinements of the final report and working with EPA to complete the upload of the database to STORET.

The study objectives are as follows:

1. Objective 1 (NY/NJ Harbor sediment survey)

Determine whether there are statistical differences in the areal extent and levels of sediment contaminants, sediment toxicity, and condition of benthic macroinvertebrate assemblages in the NY/NJ Harbor between 2008 and 2013.

2. Objective 2 (Intensive survey of 4 WWTP receiving waters)

Conduct bacteriological water and sediment contaminant sampling in the waterbodies that receive the discharge from the following wastewater treatment plants (WWTPs) or pump stations in NY and NJ. The current data from these WWTPs will be compared to standards and previously collected data.

- a. Bay Park WWTP
- b. Middlesex County Utilities Authority, NJ pump stations (2)
- c. Passaic Valley Sewerage Commission
- d. Yonkers WWTP

3. Objective 3 (Freshwater biological sampling)

Determine whether there are statistical differences in the condition of benthic macroinvertebrate communities in the freshwater portions of NJ Water Management Areas (WMAs) 4, 7, 9, and 12 by comparing current results with historical data.

B. Statistical Design of POTW Study (Task 4)

Because there is no comprehensive national baseline data set for POTW nutrient removal performance, EPA is considering a survey that would include multi-phase sampling with a screener, detailed questionnaire, and monitoring of POTWs and possibly nearby ambient waters. From EPA's bio-solids survey, EPA has a sampling frame, for another project under Contract EP-W-09-024, that need to be statistically evaluated and possibly modified for use in the POTW Study. EPA also requires support in developing a sample design and documentation for the survey. None of the data will be CBI.

C. Statistical Analysis of Monitoring Data (Task 5)

Throughout the year (i.e., period of performance), EPA occasionally needs statistical support on a quick turn-around basis for initiatives under the Clean Water Act. Such projects tend to focus on a relatively small issue that can be addressed with relatively low effort within 2-4 weeks. EPA

will identify the datasets and analysis objectives related to monitoring data. None of the data will be CBI.

Task 1: Work Plan and Cost Estimate

The contractor will provide a work plan that describes the support that will be provided; identifies deliverables; and identifies potential problems that may arise in completing this work assignment on schedule and within budget. The work plan shall individually identify the estimated LOE and costs separately for each of the tasks on the WA.

The contractor shall provide overall work assignment management and interface with the EPA WACOR.

TASK 1 – DELIVERABLES	
Deliverable	Due Date
Work plan	• Due 30 calendar days following receipt of Work Assignment.
Interface with EPA WACOR	• As needed

Task 2: Quality Assurance

Quality Assurance Project Plans are required under the Agency’s Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-0. All projects that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

QA Project Plan Requirements

EPA policy requires that an approved Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental data. In addition to abiding by its own Quality Management Plan, the contractor shall adhere to the following requirements for:

- Task 3 (NY/NJ Harbor support), the contractor shall adhere to “Quality Assurance Project Plan: Post-Super Storm Sandy (SSS) Water Quality Monitoring in Coastal New Jersey and New York (“SSS QAPP”).” Unless already provided to EPA, the contractor shall provide the EPA WACOR with copies of the QAPP certification page signed by the contractor’s QAO, the contract’s project manager, the work assignment leader, and any other person providing substantial support to the task.
- Task 4 (POTW Study), the contractor shall adhere to a project-level QAPP or, upon receiving technical direction, shall develop a QAPP for the statistical activities described in Task 5. If the EPA WACOR provides technical direction that revisions are determined to be necessary, the contractor shall submit a revised QAPP, including the revision summary, within 10 to 15 work days, depending on the complexity of the changes. When preparing this revised version, the contractor shall ensure that it is written in an active voice and shall include a version history page that summarizes changes made. The contractor shall also provide the revised QAPP in track changes and compare document. The contractor also shall provide EPA with copies of any modified SOPs or checklists.

The EPA WACOR shall formally accept these for project records by providing a signature page that includes the EPA WACOR's and EPA QAO's signatures. EPA shall review the revised QAPP and provide the contractor with written approval or comments. The contractor shall provide a final revised QAPP responding to any EPA comments within 10-15 work days of receiving EPA's comments.

- Task 5 (Quick Response), the contractor shall adhere to the contractor's QMP. Because the contractor will only provide limited support that will be reviewed by EPA statistician(s), EPA has determined that QAPPs are not necessary for these tasks.

Additional QA Documentation Required

In addition to the QAPP requirements described above and already required by Task 2, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

For any QAPP developed under this work assignment, the contractor shall verify that the QAPPs:

- Addresses all activities identified in this PWS that involve the **generation** (including field studies, laboratory studies, and modeling output), **collection** (including surveys, literature searches, and third party data), **evaluation** (including data inspection, review, assessment, and validation), **analysis** (including statistical, engineering, and economic analysis and testing, evaluation, and validation of methods and models) **and use of data** to support EPA decisions, regulations, policy, publications or tools (including effluent guidelines, methods, criteria, standards, environmental assessments, and models, tools, or reports disseminated by EPA to assist other organizations in implementing environmental programs). Examples of data include, but are not limited to, wastewater sample analysis results, flow measurements or data, facility questionnaire data, economic data, field sample data and laboratory analyses results, use of models, secondary data (including sources and the acceptance criteria), any software and database management requirements and any other relevant work that might affect the quality of the data. Note that QAPPs are also required for the development or revision of models and software that support the generation, collection, evaluation, analysis or use of data. For example, when existing models are used as a tool to generate or evaluate data, the project QAPP must describe the model, how it shall be used, and how the model output shall be evaluated to ensure it meets the overall quality objectives for the project. However, development or revision of new models also must be supported by a QAPP that describes the objectives for the model, the quality criteria that shall be applied to the model, and the procedures for evaluating whether the model meets those criteria.
- Provides enough detail to clearly describe objectives of the project supported by the work assignment; the type of data to be collected, generated, or used under this work assignment to support the project objectives; the quality objectives needed to ensure that these shall support the project objectives; and the quality assurance and quality control activities to be performed to ensure that any results obtained are documented and are of the type, quality, transparency, and reproducibility needed.

- Includes specific performance criteria and measures that shall be used to verify that data generated, collected or used in this work assignment meet those criteria. If a database or other electronic tool (e.g., model, spreadsheet, etc.) shall be created for the project, the QAPP must describe how the database or electronic tool shall be documented (e.g., data element dictionary, user manual, SOP, or other means appropriate for the project), the controls to ensure accurate data entry (when data from another source are manually entered into the database), data transfer (when data are transferred from one electronic medium to another), or data merging (when data from multiple databases or electronic media are merged into a single database).
- Explicitly references tools, such as SOPs, checklists, and guidelines that the contractor shall use in the project to document data quality. The QAPP must include the tools as attachments for EPA's review and acceptance.
- Addresses the following general questions:
 - What is the objective/goal of this effort?
 - What are the roles and responsibilities of staff who shall support this project, and how to they relate to the specific key steps?
 - What training and competency requirements are necessary for key personnel that shall support the project?
 - If models shall be used to support the project, what are these models, why have they been selected, and how shall they be validated, documented, and used?
 - What are the SOPs, tools and checklists that shall be used?
- **Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed without an approved QAPP (or addendum) in place 50 work days after submission of the contractor's work plan.**
- Under no circumstances shall field sampling or laboratory analysis activities be conducted prior to receipt of an approved work plan.
- Any non-sampling/non-analytical work that involves the generation, collection, evaluation, analysis, or use of environmental data that is initiated prior to approval of the contractor's QAPP must be performed in accordance with the approved QAPP. (The QAPP requirements must be applied retroactively to this period that lasts no more than 50 work days from submission of the contractor's work plan).

Data Quality Act/Information Quality Guidelines Requirements

The Data Quality Act (also known as the Information Quality Act) requires EPA to ensure that influential information disseminated by the Agency is sufficiently transparent in terms of data and methods of analysis that the information is capable of being substantially reproduced. To support compliance with these data transparency/data reproducibility requirements, EPA plans to include QAPPs as part of any rulemaking record documentation to be made available to the public.

Information contained in the approved QAPP must be transparent and reproducible and meet the requirements of the Data Quality Act for influential information. EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008, October 2002), referred to as "EPA's Information Quality Guidelines," describe EPA procedures for meeting Data Quality Act

requirements. Section 6.3 of EPA’s Information Quality Guidelines indicate that “especially rigorous robustness checks” should be applied in circumstances where quality-related information cannot be disclosed due to confidentiality issues. Where applicable, the contractors should indicate which results were obtained using the tools (SOPs, checklists, and guidelines) that the contractor designates as confidential so that the EPA WACOR can easily identify the areas that shall require rigorous robustness checks and document that those checks have been performed.

Additional QA Documentation Required

In addition to the QAPP requirements described above, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) produced by the contractor under this work assignment must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The contractor also shall provide EPA with monthly reports of QA activities performed during implementation of this work assignment. For each of Tasks 3 to 7, these monthly QA reports shall identify QA activities performed to support implementation of this work assignment, problems encountered, deviations from the QAPP, and corrective actions taken. If desired, the contractor may include this as a part of the contract-required monthly financial/technical progress report. In addition, the contractor shall provide timely notification to the EPA WACOR of any QA problems that may affect the conduct of the tasks, with recommendations for corrective actions.

TASK 2 – DELIVERABLES	
Deliverable	Due Date
Signed QAPP certification pages for SSS (Task 3) and, if provided, project-level POTW Study (Task 4)	Any new assigned personnel to the projects, who will provide substantial support, have 5 work days from start of the assignment.
QAPP for statistical support for POTW Study	The first draft is due 15 work days after receiving technical direction. Revisions and final version are due in 1-10 work days, depending on complexity, as specified in technical direction.
QA/QC section in all major deliverables	Per schedule for major deliverables
QA/QC progress reports	One per month per task (may be included in progress report)
Email identifying QA/QC issues and recommended action	Timely notification when EPA WACOR input is required for proceeding on task.

Task 3: Statistical Analysis of Sediment Data NY/NJ Harbor System

The contractor shall not proceed with this task until the EPA WACOR issues technical direction. The contractor shall provide statistical analysis support for the Region 2 NY/NJ Harbor Project Information for Sediment Quality of the NY/NJ Harbor System.

The contractor shall

- a. Continue to compile and statistically evaluate NY/NJ data from Task 10 of Contract EP-W-09-024. The contractor shall:
 - i. Provide interim draft outputs from ongoing statistical analyses for EPA review and input.
 - ii. Provide interim databases for EPA use.
 - iii. Provide a draft report which provides and describes the data, compares data between years, and presents the statistical results with their interpretation. At a minimum, the memorandum shall describe the data, methodology, assumptions, results, quality assurance, conclusions, and recommendations for additional research. The contractor shall provide sufficient details and clarity in the report so that the work will be transparent and reproducible. The contractor shall revise the report to incorporate the EPA WACOR's written comments.
 - iv. Provide a final version that incorporates high quality graphics and stock photographs that are:
 - Formatted in JPEG or TIFF format (300 dots per inch or higher); and
 - Accompanied with captions.
 - v. Participate in weekly 90-minute teleconferences to discuss the progress and results. The contractor must include its statistical expert(s).
 - vi. Provide supporting materials which shall include final versions of data listings, spreadsheets, computer programs, and, if appropriate, flowcharts showing relationships between them.
 - vii. Upload the final database into WQX.

Track and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

Task 3 – DELIVERABLES		
Subtask	Deliverable	Due Date
a. Implementation	Interim draft analyses	Two days prior to teleconference for which EPA and the contractor will discuss the outputs.
	Draft databases	5 work days after receiving technical direction.
	Report	The first draft is due 15 work days after receiving technical direction to start the task. Revisions and final version are due in 1-10 work days, depending on complexity, as specified in technical direction.
	Teleconference	The EPA WACOR will schedule the date and time upon consultation with the contractor, and cancel as appropriate.
	Supporting documentation	5 work days after receiving technical direction.

Task 3 – DELIVERABLES		
Subtask	Deliverable	Due Date
	WQX upload	5 work days prior to end of period of performance or 10 work days after EPA accepts the final report
b. Tracking	Technical progress, LOE, and cost reports	Monthly with progress report.

Task 4. POTW Study

The contractor shall not proceed with this task and each subtask until the WACOR issues technical direction. The contractor shall:

- a. Evaluate the sample frame provided by the WACOR, which includes the Targeted National Sewage Sludge Survey (TNSSS) bio-solids sample frame. (EPA will provide documentation and databases from the bio-solids sample frame used in Contract EP-C-05-030 and WA 4-4 in Contract EP-W-09-024 and the added information that compiled under a separate effort.) Provide a written assessment of the sample frame and the ease of using it to develop a sampling plan. Identify any deficiencies and recommend actions to remedy them.
- b. Design statistical sampling plans for the POTW study. The contractor shall design these plans to achieve EPA's goals and objectives for statistical inferences about the populations. The contractor shall estimate and technically evaluate the precision associated with the sampling plans, the subpopulations in the strata, and post-stratification. The contractor also shall include recommendations in the sampling plans for identifying and handling anomalies. The contractor shall estimate the burden and costs for the respondents and EPA of implementing the sampling plans. The contractor shall attend up to four 1-day meetings to discuss study objectives at EPA HQ and participate in weekly teleconferences discussing objectives and progress.
- c. Provide statistical review, comment, and analysis of survey designs (e.g., from industry) provided to the contractor by EPA. The contractor shall technically evaluate whether the survey designs will achieve EPA's objectives and allow for statistical inferences from the results.
- d. Provide review and comment on drafts of survey instruments, related letters, and supplemental information to ensure that EPA is collecting the necessary information to execute the sampling plan. The contractor shall evaluate each survey instrument for clarity, content, design, format, structure, and consistency with EPA's objectives.
- e. Draft portions of statistical documentation of ICR packages that shall be consistent with EPA objectives, the Paperwork Reduction Act, Executive Order 12866, and Office of Management and Budget requirements.

Track and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

Task 4 – DELIVERABLES		
Subtask	Deliverable	Due Date
a	Memo with sample frame recommendations	5 work days after receiving technical direction. Revisions within 2-15 work days depending on complexity and urgency.

Task 4 – DELIVERABLES		
Subtask	Deliverable	Due Date
b	Sampling plans	15 work days after receiving technical direction. Revisions within 2-15 work days depending on complexity and urgency, per technical direction. EPA WACOR will schedule dates and times upon consultation with the contractor, and cancel as appropriate.
	Meetings	EPA WACOR will schedule dates and times upon consultation with the contractor.
	Teleconferences	EPA WACOR will schedule dates and times upon consultation with the contractor, and cancel as appropriate.
c and d	Memo with reviews	5-10 work days depending on complexity and urgency, per technical direction.
e	Draft ICR sections and supporting documents	5-10 work days depending on complexity and urgency, per technical direction.
f	Technical progress, LOE, and cost reports	Monthly with progress report.

Task 5 Quick Response Statistical Analyses of Monitoring Data

The contractor shall not proceed with this task until the EPA WACOR issues technical direction. The contractor shall determine and apply appropriate statistical procedures and methodologies in analyzing and interpreting monitoring data. The types of methodologies shall include, but not be limited to: nonparametric statistics, multivariate analysis, regression analysis, maximum likelihood estimation, analysis of variance, time series, categorical data analysis, survey statistics, inferential statistics, spatial analysis, survival analysis, statistical meta-analysis, and graphical analysis. The contractor shall clearly specify the methods, procedures, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document the reasons for selecting particular procedures, methodologies, and assumptions; and alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. EPA will review all outputs and provide agency input/changes. The contractor shall incorporate the changes specified by EPA. The contractor shall track and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

Task 5 – DELIVERABLES	
Deliverable	Due Date
Statistical Analysis (memo)	Within 1-10 work days, depending on complexity, as specified in technical direction. Revisions within 1-5 work days, depending on complexity, as specified in technical direction.
Programs and input data files	Within 5 work days after receiving technical direction.

Task 5 – DELIVERABLES	
Deliverable	Due Date
Technical progress, LOE, and cost reports	Monthly with progress report.

II. TRAVEL: The contractor shall attend up to three 1-day meetings in Washington, DC in support of Task 4.

III. PERIOD OF PERFORMANCE: This work assignment will start on the date of the contracting officer's signature and extend through the following 365 days.

IV. ESTIMATED LEVEL OF EFFORT: 400 hours

V. EPA CONTACTS:

Work Assignment Contracting Officer Representative (WACOR):

Brian Schnitker
Phone: 202-566-0838
e-mail: schnitker.brian@epa.gov

Alternate WACOR:

Paul Shriner
Phone: 202.566.1076
e-mail: shriner.paul@epa.gov

USPS Address (for WACOR):

U.S. EPA (4503T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Overnight Courier Address (for WACOR):

U.S. EPA
7313C EPA West
1301 Constitution Avenue, NW
Washington, DC 20004

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 0-06				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2017 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name Chemical Hazard and Exposure				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2016 To 06/12/2017				
Comments: The purpose of this action is to initiate this work assignment and add hours as detailed below. The contractor shall provide a work plan and cost estimate in accordance with the terms of the contract.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE: 0					
06/13/2016 To 06/12/2017										
This Action:					1,180					
Total:					1,180					
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Jeffrey Taylor <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-8828 FAX Number:			
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name Brian Nelson-Palmer <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-6190 FAX Number:			
Contracting Official Name Sheila Dolan <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4348 FAX Number:			

Work Assignment Form. (WebForms v1.0)

Contract Number: EPW16017

Work Assignment Number: 0-06

Title: Chemical Hazard and Exposure Evaluation and Risk Management

Purpose:

This work assignment continues and expands upon the work initiated under Work Assignment 4-02 of Contract EP-W-09-024. No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled *Chemical Hazard and Exposure Evaluation and Risk Management*, was developed to provide EPA with support in analyzing existing chemicals and pursuing work for those chemicals that have the highest risk.

EPA's Existing Chemicals Program addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high risk, EPA will choose from among many actions that it is authorized to take under the current Toxic Substances Control Act (TSCA). The Agency may pursue such regulatory actions as: restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The contractor shall prepare and submit a technical and financial work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Subtask 2. Rulemaking Support

The contractor shall help EPA develop rules, such as TSCA section 4 test rules that secure additional chemical data, section 5 Significant New Use Rules (SNURs) that deal with new uses, and section 6 rules that restrict chemicals. Work may include analyzing literature sources, or managing information that was developed by EPA or outside entities (e.g., other agencies, states, countries, NGOs, foundations, universities, and companies). The contractor may help collect, organize, and summarize public comments that are submitted by entities such as public interest groups, industry, academia, and others to EPA rulemaking dockets.

Subtask 3. Meeting & Workshop Support

The contractor shall assist EPA with meeting support by taking notes during meetings, such as at weekly one-hour division director-level meetings, at periodic and variable-length EPA rulemaking meetings, and/or at rulemaking consultation meetings that deal with tribal, small business, and state issues. The

contractor will produce the meeting/workshop notes and also incorporate any edits to those notes provided by EPA. Additional support may be conducted for expert meeting workshops, and may require the contractor to solicit attendees, organize logistics, facilitate the workshop, and summarize the discussions that take place at the workshop.

Subtask 4. Chemical Prioritization & Work Plan Chemicals

The contractor may assist EPA with identifying priority chemicals for risk management analysis. Work could include securing lists of chemicals that are being analyzed by: other countries, states within the United States, and EPA or other Federal agencies. The contractor may present information related to hazard, exposure, risk, and different environmental mediums such as air, water, and soil. The contractor may help EPA identify and take follow-up action on Work Plan chemicals that generally have the greatest risk concerns.

Subtask 5. Chemical Data Reporting (CDR)

The contractor may assist EPA with managing chemical data under its CDR. Support can include working with the 2016 CDR and 2012 CDR, helping with Internet and outreach materials, and producing statistics and chemical lists that relate to production volume, companies, industrial processing and use, and consumer and commercial use, among other information.

Subtask 6. High Production Volume (HPV) Chemical Management

The contractor shall continue to maintain HPV Challenge Program records, and conduct queries on HPV Challenge Program data if needed. The contractor may also perform work with other HPV chemicals.

Subtask 7. Miscellaneous Hazard, Exposure, and Risk Analyses

The contractor shall conduct analyses regarding other miscellaneous hazard, exposure, and risk management projects as the need arises.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Rulemaking Support	At WAM's Request.
Subtask 3.	Meeting & Workshop Support	At WAM's Request.
Subtask 4.	Chemical Prioritization & Work Plan Chemicals	At WAM's Request.
Subtask 5.	Chemical Data Reporting (CDR)	At WAM's Request.
Subtask 6.	HPV Chemical Management	At WAM's Request.
Subtask 7.	Miscellaneous Hazard, Exposure, & Risk Analyses	At WAM's Request.

- EPA will approve the work plan within 45 days.
- A QA plan is required.
- A work plan is required.
- CBI does apply.

- The work assignment relates to: Task II, Subtask 1; Task III, Subtasks 1, 8, and 13; and Task IV, Subtask 3 of the contract SOW.

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through April 27, 2016.

V. Level of Effort:

The level of effort described in this work assignment shall not exceed 1,180 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative

Jeffrey Taylor
WJC East Building, Rm 4134-E, MC 7405M
1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-8828
taylor.jeffrey@epa.gov

Alternate Contracting Officer Representative

Tyler Lloyd
WJC East Building, Rm 4121-K, MC 7405M
1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-4016
lloyd.tyler@epa.gov

Contract Number: EP-W-16017

Work Assignment Number: 0-06

Title: Chemical Hazard and Exposure Evaluation and Risk Management

Purpose:

To increase the level of effort by 1,430. All the tasks will stay the same.

I. Background:

This work assignment, entitled Chemical Hazard and Exposure Evaluation and Risk Management, was developed to provide EPA with support in analyzing existing chemicals and pursuing work for those chemicals that have the highest risk.

EPA's Existing Chemicals Program addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high risk, EPA will choose from among many actions that it is authorized to take under the current Toxic Substances Control Act (TSCA). The Agency may pursue such regulatory actions as: restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The contractor shall prepare and submit a technical and financial work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Subtask 2. Rulemaking Support

The contractor shall help EPA develop rules, such as TSCA section 4 test rules that secure additional chemical data, section 5 Significant New Use Rules (SNURs) that deal with new uses, and section 6 rules that restrict chemicals. Work may include analyzing literature sources, or managing information that was developed by EPA or outside entities (e.g., other agencies, states, countries, NGOs, foundations, universities, and companies). The contractor may help collect, organize, and summarize public comments that are submitted by entities such as public interest groups, industry, academia, and others to EPA rulemaking dockets.

Subtask 3. Meeting & Workshop Support

The contractor shall assist EPA with meeting support by taking notes during meetings, such as at weekly one-hour division director-level meetings, at periodic and variable-length EPA rulemaking meetings, and/or at rulemaking consultation meetings that deal with tribal, small business, and state issues. The contractor will produce the meeting/workshop notes and also incorporate any edits to those notes provided by EPA. Additional support may be conducted for expert meeting workshops, and may require

the contractor to solicit attendees, organize logistics, facilitate the workshop, and summarize the discussions that take place at the workshop.

Subtask 4. Chemical Prioritization & Work Plan Chemicals

The contractor may assist EPA with identifying priority chemicals for risk management analysis. Work could include securing lists of chemicals that are being analyzed by: other countries, states within the United States, and EPA or other Federal agencies. The contractor may present information related to hazard, exposure, risk, and different environmental mediums such as air, water, and soil. The contractor may help EPA identify and take follow-up action on Work Plan chemicals that generally have the greatest risk concerns.

Subtask 5. Chemical Data Reporting (CDR)

The contractor may assist EPA with managing chemical data under its CDR. Support can include working with the 2016 CDR and 2012 CDR, helping with Internet and outreach materials, and producing statistics and chemical lists that relate to production volume, companies, industrial processing and use, and consumer and commercial use, among other information.

Subtask 6. High Production Volume (HPV) Chemical Management

The contractor shall continue to maintain HPV Challenge Program records, and conduct queries on HPV Challenge Program data if needed. The contractor may also perform work with other HPV chemicals.

Subtask 7. Miscellaneous Hazard, Exposure, and Risk Analyses

The contractor shall conduct analyses regarding other miscellaneous hazard, exposure, and risk management projects as the need arises.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Rulemaking Support	At WAM's Request.
Subtask 3.	Meeting & Workshop Support	At WAM's Request.
Subtask 4.	Chemical Prioritization & Work Plan Chemicals	At WAM's Request.
Subtask 5.	Chemical Data Reporting (CDR)	At WAM's Request.
Subtask 6.	HPV Chemical Management	At WAM's Request.
Subtask 7.	Miscellaneous Hazard, Exposure, & Risk Analyses	At WAM's Request.

- EPA will approve the work plan within 45 days.
- A QA plan is required.
- A work plan is required.
- CBI does apply.
- The work assignment relates to: Task II, Subtask 1; Task III, Subtasks 1, 8, and 13; and Task IV, Subtask 3 of the contract SOW.

IV. Period of Performance:

This Work Assignment began with the date of the Contracting Officer's signature and extends through June 12, 2017.

V. Level of Effort:

The level of effort described in this work assignment amendment shall not exceed 1,430 professional hours. These 1,430 hours are in addition to the base 1,180 hours that were referenced at the beginning (06/12/16) of the work assignment period of performance.

VI. EPA Contacts:

Primary Contracting Officer Representative

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1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-8828
taylor.jeffrey@epa.gov

Alternate Contracting Officer Representative

Tyler Lloyd
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1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-4016
lloyd.tyler@epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 0-07				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2017 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name Predictive Mathematical Model				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2016 To 06/12/2017				
Comments: The purpose of this action is to initiate the work assignment and adjust the hours of LOE as detailed below. Contractor shall submit a work plan and cost estimate in accordance with the terms of the contract.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2017										
This Action:						315				
Total:						315				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name Tony McDonald <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-1476 FAX Number:				
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name Brian Nelson-Palmer <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-6190 FAX Number:				
Contracting Official Name Sheila Dolan <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4348 FAX Number:				

Battelle EPW16017
Work Assignment 0-07

Title: Predictive Mathematical Modeling of Water Contaminant Mixture Data

Purpose: The Work Assignment (WA) is to provide statistical expertise and modeling in support of mixtures and grouping research being conducted under the Safe and Sustainable Water Research (SSWR) National Research Program of the U.S. EPA. Specifically, this WAM is for statistical effort to: revise, based on new experimental design considerations, previously determined power calculations and sample size estimates for pre-determined effect magnitudes for health endpoints; extend the development and examination of approaches to discern the contributions of individual chemicals and chemical groups to the toxicity of a chemical mixture; conduct statistical analyses to examine the hypothesis that the toxicity of a group of chemicals can be predicted based on knowledge of the dose-response curves of the chemicals contained in the mixtures; to develop, where needed, novel approaches, methods and analyses for grouping chemicals and to enhance understanding of the joint toxic actions of groups of chemicals.; and, to provide expert consultation and advice in interpretation of results of analyses of chemical mixtures and groups.

I. Background:

While the need for toxicological research with both defined and complex mixtures of disinfection byproducts (DBPs) and other chemical contaminants of water is recognized, the lack of broadly-recognized appropriate statistical methods both to design appropriate experiments (e.g. power calculation methods to determine appropriate samples sizes to detect differences between treated groups and controls, if such differences exist) and the lack of broadly-recognized methods to determine when the effect of defined mixtures of chemicals deviates from that expected under an assumption of dose additivity, has hindered the ability to develop data needed by EPA to evaluate the potential human health risk that might be associated with exposure to the low levels of chemicals detected in water and to those chemicals formed or transformed during disinfection of water (DBPs, transformation DBPs).

Under the Safe and Sustainable Water National Research Program (SSWR), EPA is conducting a series of studies to understand the toxicity of groups of DBPs and transformation DBPs. DBPs and transformation DBPs are chemicals formed or transformed during the disinfection of drinking water. DBPs have been associated with adverse health effects through epidemiological and toxicologic studies. In addition to DBPs, candidate contaminant list (CCL) chemicals and chemicals of emerging concern (CECs) are interest, both individually and as groups. Studies at EPA are addressing different source waters and source water characteristics, different drinking waters (CCL and DBP focus) and wastewater treatments (CCL and DBP focus), with regard to the contaminants present and their concentrations, DBPs formed and their concentrations, and the relative toxic potency of the mixtures. Understanding those contaminants and contaminant groups that pose the greatest risks to human and ecological health will allow risk management and remediation efforts to focus on those that provide the greatest reduction in risk. Integrating toxicological assessments into risk remediation and reduction research provides immediate and

valuable feedback into those treatments/remedial activities that actually reduce health risk.

Predictive models for estimating the effects of contaminants groups will be used or developed/ revised where necessary and then used that have the ability to forecast the effects of contaminant groups from single chemical data, creating models that are predictive even when mixture composition changes (fewer chemicals in the mixture, more chemicals in the mixture, the mixing ratio changes as the mixture moves downstream or through the water system). The goal is to develop flexible and accurate predictive models for estimation for toxicity of contaminant groups that allow for addition and deletion of contaminants and varied specification of chemical concentrations (to enhance usefulness across a spectrum of situations).

II. Scope of Work

The EPA WAM will identify the specific deliverables, corresponding delivery dates, and provide additional technical clarification/directives regarding the tasks of the work assignment listed below through written technical directives (except for tasks 1, 2, and 3). Each initial deliverable shall be provided to the EPA WAM in draft form for review and comment. The contractor shall incorporate procedures to ensure that these drafts completely document the methodologies; use appropriate assumptions; are accurate, complete, and as specified in the work assignment or written technical direction before providing them to the EPA. The contractor shall incorporate EPA review comments into revisions of the drafts. All drafts and final reports shall be approved by the EPA WAM. A work plan is required (Task 1) and a QA/QC plan is required (Task 2). CBI does not apply to this WAM. This work assignment relates to the current Statement of Work (SOW) of the contract.

1. Workplan

The contractor shall prepare a work plan for each task in this work assignment before embarking on work on that particular task. The EPA WAM will inform the contractor of the EPA priorities with regard to conduct of each task. The work plan must provide the QA/QC elements will be observed during the conduct of this work assignment. These include that before conducting analyses the contractor shall provide the EPA the summary statistics of the data that are being planned for analysis, consisting of sample means, sample standard deviations and sample size for each dose group and that potential data quality issues be presented to EPA prior to proceeding further. The final report shall include a detailed description of all methods used; the results of any analyses conducted, including confidence intervals, statistical significance, multiple comparisons (as appropriate); for any data analyses conducted, summary statistics of the data generated from the final program used to analyze the data shall be provided with the summary statistics consisting of sample means, sample standard deviations and sample size for each dose group and the programs used for analysis.

2. Review Background Documentation

The contractor shall review background documentation about the project. The EPA will provide publications and draft manuscripts that describe the Four Lab Study in detail, including all results

to date. Additionally, the EPA will serve as a resource for relevant literature and background materials relevant to completion of the tasks.

3. Attend Kick-off Teleconferences

The contractor shall participate in a teleconference to address any questions that the contractor may have regarding the scope and goals of tasks 6, 7, 8 and 12 and discuss the data, analytic requirements, relevant background information and available literature. A teleconference shall be conducted specific to each of tasks 6, 7, 8 and 12. Additionally, the contractor shall prepare summary notes which clearly summarize the teleconferences.

4. Data Quality

The contractor shall assess databases to evaluate their data quality and integrity. The contractor shall identify outliers and questionable data by reviewing data listings and summaries, applying statistical methods, and using graphical methods. The contractor also shall review the data for missing values, censoring patterns, and appropriate units of measure (e.g., milligrams/liter). Prior to use of the data, the contractor shall supply the EPA with summary data for each dose group proposed for inclusion in the analysis, including the dose level, n, mean and standard deviation and identify the specific source of the data.

5. Experimental Design Recommendations

The contractor shall provide expert consultation in considering the impact of statistical power and data transformations for experiments involving defined and complex mixtures of chemicals.

The contractor shall focus on the low dose / low effect region of the dose-response curve. In particular, the differential power associated with the logit and the arcsine square root transformation shall be considered for proportion data. The contractor shall refine, as necessary, power calculations and sample size estimates for pre-determined effect magnitudes for health endpoints in rats, for the priority endpoints of pup weight, prenatal loss, in vitro fertility, male and female sexual maturation, and cardiac defects. The contractor shall provide a report containing these results.

6. Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture and Provide Expert Consultation on Interpretation of Results

Using both data and reports furnished by the U.S. EPA, the contractor shall provide expert consultation with regard to mixtures analyses and, as directed, conduct statistical analyses to evaluate consistency with dose addition and estimate the contribution(s) of individual chemicals and chemical groups to the toxicity of a chemical mixture. The contractor shall also provide expert consultation that provides insights into the interpretation of the results of statistical analyses of mixtures data. The first effort under this task shall consider in vivo toxicity data on individual trihalomethanes (chloroform, bromodichloromethane, chlorodibromomethane,

bromoform) and the six possible binary combinations of these four chemicals. These data will be examined for suitability of analysis by the expected component contribution score described by Hertzberg et al 2013 (*Toxicology*, 2013 (November) 313:134-144. The second effort consists of in vitro toxicity data on up to 10 haloacetic acids and haloacetic acid mixtures consisting of a varied number of chemicals, developed in vivo, in vitro and ex vivo assays. Additional efforts will involve data sets transmitted by the U.S. EPA and discussed in detail with the contractor. The contractor shall determine, for data sets provided by the EPA, whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions and models more closely approximate the observed mixture response.

7. Review peer-reviewed publications that describe the analysis of mixtures data and determine the suitability of the experimental design, the analysis and the conclusions.

It is well known that many mixtures experiments that have been published in the peer-reviewed literature are lacking in design, in analysis or in interpretation, such that the conclusions drawn from the studies may not be appropriate. The contractor shall review selected studies provided by the EPA and examine them for appropriateness of experimental design, statistical analysis and the interpretation of the results provided in the publications. Where feasible the data will be analyzed by alternative methods, with methods subject to approval by the EPA. Also, where possible, quantitative metrics of deviation from additivity will be derived, in those cases where deviation from additivity is detected.

8. Develop computer programs

The contractor shall ensure that all databases, computer programs, and the corresponding documentation developed under this contract are accessible to the EPA Project Officer, the EPA WAM, and persons authorized by them. The contractor shall provide this computer programming support to technically support the statistical analysis specified in other areas of this statement of work. All computer programs shall be well documented internally to facilitate EPA's review. Furthermore, the contractor shall use SAS, the Agency standard software for statistical analysis.

9. Internal Documentation

The contractor shall internally document all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code so that results can be replicated even if the originating staff members are no longer available. The contractor shall provide access to this internal documentation upon request by the EPA WAM. This documentation shall provide the foundation of the documentation of the products to be produced in the other areas of this Work Assignment (see #10)

10. Prepare documentation

The contractor shall provide documentation for products in the other areas of this Work

Assignment. The contractor shall provide documentation in computer files, and in hardcopy, upon specific request. The contractor shall incorporate EPA comments into revisions of the draft documentation. In all cases, the statistical algorithms and data used to generate results shall be provided electronically as well as in the appendix of the draft and final reports. The documentation shall include all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code used in accomplishment of the work effort.

In any documentation, the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. Further, the documentation shall be labeled with the name of the contractor, the EPA contract number (EPW16017) and the work assignment number (0-07).

IV. Period of Performance: This work assignment will start on the date of the contracting officer's signature and extend through the period of performance of the contract.

V. Level of Effort: This work assignment shall require a total of 315 professional hours. Clerical hours are not included

VI. EPA contacts

Work Assignment Manager:

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Integrated Systems Toxicology Division
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e-mail: McDonald.Tony@epa.gov

Alternate Work Assignment Manager:

Mike Hughes
Pharmacokinetics Branch
Integrated Systems Toxicology Division
National Health and Environmental Effects Research Laboratory
U.S. Environmental Protection Agency
MD B105-03, 109 T. W. Alexander Drive
Research Triangle Park, NC 27711
Phone: 919-541-2160
e-mail: Hughes.MichaelF@epa.gov

V. Deliverables and Schedule

The following is a list of the deliverables required under this Task Order.

<u>Task</u>	<u>Deliverable</u>	<u>Date</u>
1	Initial Work plan	Due 15 days following receipt of Work Assignment (WA)
2	Knowledge about previous statistical work (i.e., contractor needs to read background materials).	Start upon receipt of the WA
3	Kick-Off Teleconferences for Tasks 5 and 6	At the beginning of work on each task at a time mutually agreement to EPA and the contractor. First Teleconference to take place within 4 weeks of receipt of the WA
4	Electronic files with the statistical analyses and quality assurance evaluations, computer programs, draft and final documentation (memoranda, reports) of results and methods used. Hardcopies, if requested in technical direction.	Following technical direction from the WA. Revisions delivered as specified in technical directions.
5	Experimental Design Recommendations	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 30 days after request delivered and subsequent kick-off teleconferences*
6	Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture and Provide Expert Consultation on Interpretation of Results	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 30 days after request delivered and subsequent kick-off teleconferences*

<u>Task</u>	<u>Deliverable</u>	<u>Date</u>
7	Review peer-reviewed publications that describe the analysis of mixtures data and determine the suitability of the experimental design, the analysis and the conclusions.	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 45 days after request delivered and subsequent kick-off teleconferences*
8	Briefings on Results of Tasks 5, 6, and 7	Within 3 weeks of contractor providing the draft reports as specified for each task.
9	Computer programs and Documentation	As identified for other areas of the SOW.

* These dates may be modified by technical direction, rather than requiring workplan modification.

VI. OTHER REQUIREMENTS

The contractor shall provide written notification to the contracting officer, project officer, and work assignment manager when 75 percent of the hours and/or funds have been spent on this work assignment.

The contractor also shall immediately contact the EPA WAM to discuss any problems that may adversely affect the work on this work assignment.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 0-07				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2019 To 06/12/2020 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name Mathematical Modeling of Water				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2016 To 06/12/2017				
Comments: The purpose of this amendment in to increase the LOE hours by 286. The CS is John Moua, PO is Cynthia Bowie and the Work Assignment Manager is Tony McDonald. The contractor shall provide a workplan approval within 15 day of receipt of this work assignment amendment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 315				
06/13/2019 To 06/12/2020										
This Action:						0				
Total:						315				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name Tony McDonald <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-1476 FAX Number:				
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Sheila Dolan <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4348 FAX Number:				

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 0-08				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2017 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name RRP Outreach to Contractors				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Work Plan Approval </div> <div> <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Incremental Funding </div> </div>						Period of Performance From 06/13/2016 To 06/12/2017				
Comments: The purpose of this action is to initiate this work assignment and adjust the hours of LOE as detailed below. Contractor shall submit a work plan and cost estimate in accordance with the terms of the contract.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2017										
This Action:						320				
Total:						320				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Darlene Leonard <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-0516 FAX Number:				
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name Brian Nelson-Palmer <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-6190 FAX Number:				
Contracting Official Name Sheila Dolan <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4348 FAX Number:				

Contract Number: EP-W-16-017

Work Assignment Number: 0-08

Change Number: 0

Title: RRP Lead Outreach to Contractors

I. Purpose and Background

The purpose of this Work Assignment is to provide technical support for the implementation of the Renovation, Repair and Painting Program. This work is to be performed in parallel to and in close coordination with Work Assignment Number 0-02 on Contract Number EP-W-16-017.

These two work assignments are complementary and no work shall be duplicated or repeated.

Section 402(c) of TSCA authorizes EPA to promulgate regulations governing renovation activities conducted in homes built before 1978 that produce a lead-based paint hazard. EPA promulgated these regulations at 40 CFR part 745, Subpart E.

Under TSCA Section 404, EPA may authorize any State to administer and enforce the standards, regulations, or other requirements established under TSCA Sections 402 if the State has a program that is at least as protective of human health and the environment as the program specified in TSCA and that provides adequate enforcement. EPA's implementing regulations can be found at 40 CFR part 745, Subpart Q.

Section 404(h) of TSCA requires EPA to implement and enforce a federal lead based paint program in all States and Tribal areas that do not have an authorized program. EPA is permitted to use State and Tribal Assistance Grant funds to support implement the programs. (See 40 CFR 35.116, and 40 CFR 35.516.) Under this work assignment, EPA is seeking to increase the number of renovation contractors with RRP firm certification and/or those that take RRP training from an EPA authorized training provider.

II. Scope of Work Outreach to Contractors

The Contractor shall:

- Develop a program to encourage non-certified RRP firms to become certified or to renew their RRP firm certification in the following cities: El Paso, TX, Denver, CO, Oakland, CA and Memphis, TN (plus up to 4 additional cities, as determined by the WAM). Such a program could include, but not be limited to, regular US mail, local newspapers, mass media such as television and radio, social media and other electronic communications and/or through materials distributed at/by locations frequently visited by renovation contractors to promote the requirement to and importance of becoming EPA certified and employing trained RRP contractors. This effort will be done in coordination with Work Assignment Number XX involving lead outreach events for consumers and RRP contractor training courses sessions to be conducted in the same cities. This effort must be developed in coordination with EPA Regional, state, local government as well as NGO's focused on issues regarding lead and other healthy homes issues. The effort must include some partnerships with commercial and/or public entities that is expected to last beyond the period of this task. Efforts may involve:

- Developing graphic ads, post cards, flyers, fact sheets, web banners, mailings, etc. to non-certified RRP firms by modifying existing EPA outreach materials, detailing the specific outreach event to be held in each of the 4 cities identified in this WA (and additional cities as determined by the EPA WAM).
 - Printing and placing ads for each outreach event in each of the 4 cities identified in this WA (and additional cities as determined by the EPA WAM). Utilize social media whenever possible.
 - Identification of industry and community leaders who will attest to and promote benefits of RRP compliance.
- Develop distribution plans for any developed materials (ads, postcards, flyers, fact sheets, web banners, mailings, agendas etc.) necessary to support this effort. This may include but not limited to, obtaining lists of non-certified RRP firms and coordinating with EPA Regional, state and local government lead programs to identify such firms.
 - Identify, reserve space, and pay (if required) for a venue for at least one lead outreach informational session event for non-certified RRP contractors in each city identified in this WA plus up to 4 additional cities, as determined by the WAM, to include but not limited to radio and television interviews, town hall and local meetings or events. The Contractor shall work with the EPA WAM to determine what the event will be held in each city. This effort will be done in coordination with Work Assignment Number 0-02 on Contract Number EP-W-16-017 involving lead outreach events for consumers and RRP contractor training courses sessions to be conducted in the same cities.

III. Deliverables:

- Strategy – The Contractor shall submit to the EPA WAM a strategy document that describes how non-certified RRP firms will be encouraged to become certified and how RRP firms will be encouraged to renew their certification. The strategy shall provide a detailed distribution plan that shall include lists of non-certified RRF firms in each city identified in this WA plus up to 4 additional cities, as determined by the WAM. The Contractor shall incorporate input from the EPA and state and local government lead programs to the strategy.
- Summary of Work – The Contractor shall submit to the EPA WAM a report providing statistics on the activity for the contract period. The letter shall summarize the work completed and shall include what outreach activities occurred and the number of people reached. In addition, the report will include:
 - A description of ads printed, posted on social media and placed for each outreach session in each of the 4 cities identified in this WA, plus up to 4 additional cities, as determined by the WAM.
 - A description of the actual outreach event held in each of the 4 cities identified in this WA, plus up to 4 additional cities, as determined by the WAM, including the name, location of the venue, date, and time.
 - A description of the number of firms contacted and sources used to develop list of renovation firms to contact.
 - An analysis of which outreach messages and delivery mechanism were most and least effective.

A work plan is not required. A financial plan is required.
A Quality Assurance Project Plan is not required.
CBI does not apply.

This work assignment relates to Tasks III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:

This work assignment will start on the date of the Contracting Officer signature and extend through June 16, 2017.

V. Level of Effort

This work assignment shall require no more than 320 professional hours.

VI. EPA Contacts:

Work Assignment Manager:

Darlene Leonard
US EPA National Program Chemicals Division
Program Assessment and Outreach Branch (7404T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-566-1859

Deputy Work Assignment Manager:

Julie Shannon
US EPA National Program Chemicals Division
Program Assessment and Outreach Branch (7404T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-8834

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 0-09				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2017 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name Algae Guidance for the Biotech				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 09/27/2016 To 06/12/2017				
Comments: The purpose of this action is to initiate the subject work assignment. Contractor shall provide a work plan and cost estimate in accordance with the terms of the contract.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2017				0						
This Action:				350						
Total:				350						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name Joe Avcin <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-8522 FAX Number:				
Project Officer Name Cynthia Bowie <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name Brian Nelson-Palmer <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-6190 FAX Number:				
Contracting Official Name Sheila Dolan <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4348 FAX Number:				

STATEMENT OF WORK

WORK ASSIGNMENT (WA) Title: WA 0-09, 2nd Public Meeting and Opportunity for Public Comment on Algae Guidance for the Preparation of TSCA Biotechnology Submissions

Contract No.: EP-W-16-017

Work Assignment Manager: Joe Avcin, OPPT/Risk Assessment Division Telephone: (202) 564-1811 E-mail: Avcin.Joe@EPA.Gov	Mailing Address: U.S. EPA, 1200 Pennsylvania Avenue NW, Mail code 7403M, Washington, DC 20460-0001 Courier Address: Room 6334S, WJC East Building., 1201 Constitution Ave. NW, Washington, DC 20004
Alternate Work Assignment Manager: Greg Macek, OPPT/Risk Assessment Division Telephone: (202) 564-8516 E-mail: Macek.Greg@EPA.Gov	Mailing Address: U.S. EPA, 1200 Pennsylvania Avenue NW, Mail code 7403M, Washington, DC 20460-0001 Courier Address: Room 6308UU, WJC East Building., 1201 Constitution Ave. NW, Washington, DC 20004

1.0 BACKGROUND:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed into law on June 22, 2016, amends numerous sections of the Toxic Substances Control Act (TSCA) enacted in 1976 (Ref. 1). This law imposes oversight responsibility on EPA for the production and use of GM (Genetically Modified) microorganisms.

In 1997, EPA promulgated the Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act, which implemented rules for notification to EPA of new microorganisms. Connected with this effort, EPA has developed a document, Algae Guidance for the Preparation of TSCA Biotechnology Submissions, to assist those who intent to submit pre-manufacture Biotechnology notices to EPA. The document helps submitters identify and organize key information that the Agency needs for its review.

EPA is currently drafting Algae Guidance to accommodate the development of new information relevant to risk assessment of biotechnology products regulated under the new Chemical Safety Act. As EPA develops this document, it welcomes public input not only on technical environmental assessment issues, but also on the societal benefits and implications of GM algae products.

EPA will facilitate such engagement by holding a second public meeting in the morning and a separate stakeholder workshop in the afternoon of October 27, 2016. The first public workshop was held in September of 2015. ERG provided support for that workshop under WA 5-16 of contract EP-W-10-014. Battelle Memorial Institute will provide support for this second workshop under WA 0-09 of contract EP-W-16-017. The purpose of this work assignment is for Battelle to provide support to EPA by (1) assisting with the planning and execution of the public meeting logistics; 2) serving as an additional facilitator during the workshop and providing note takers; (3) preparing a final meeting summary report; and (4) preparing a final docket comments summary.

EPA is collaborating with ECAST, who facilitates the cultivation of expert and stakeholder informed citizen perspectives and citizen priorities for democratic decision-making on science and technology issues. ECAST is made up of academics in the social sciences, emerging technologies and communication experts. The ECAST/EPA stakeholder workshop is a pre-deliberation design event that convenes diverse experts and stakeholders from the public, private, not-for-profit, and academic sectors. As such the contractor will provide support to ECAST/EPA through the contract, and will entail the preparation of packaged materials prior to the workshop and facilitator and note taking support during it, but ECAST/EPA will be in charge of workshop logistics, agendas, primary facilitation, and content.

2.0 PERIOD OF PERFORMANCE:

The period of performance for this WA shall be from date of issuance through June 12, 2017.

3.0 LEVEL OF EFFORT:

The estimated LOE for this WA is 350 hours.

4.0 TASKS

Task 1. Prepare Work Plan and Budget, Manage Work Assignment, and Administrative Tasks

This Work Assignment will involve the preparation of a work plan and budget, and the management of the Work Assignment. Under this task the contractor shall prepare a work plan within 15 calendar days of receipt of this Statement of Work. The work plan shall describe the work to be performed, the technical approaches used for the various sub-tasks, projected schedules, workshop logistics, cost information, a staffing plan, and an outline of key deliverables on a task-by-task basis with expected due dates. As per the Contract, the contractor shall provide weekly progress reports.

The contractor shall participate in a kick-off meeting to be held within 5 days of receipt of the approved work assignment. The contractor shall also provide weekly updates to the EPA Work Assignment COR and Alternate Work Assignment COR that includes a brief summary of the progress made that week, hours spent, and work planned for the following week.

Task 2. Planning and Execution of Public Meeting Activities and support for Workshop

A draft Agenda for the workshop is provided in Annex 1. The public meeting and workshop are currently being planned for the morning and afternoon of October 27, 2016 on the Arizona State University campus in Tempe, Arizona. EPA is anticipating public meeting attendance will be approximately 100-120 individuals, and the afternoon workshop to have no more than 30 participants.

Technical Direction

Technical direction throughout the period of performance will be issued by the EPA Work Assignment COR or by the Alternate Work Assignment COR. The workshop will be held in Tempe, Arizona on October 27. It is possible that the EPA Work Assignment COR and Alternate COR will not be physically on-site on the day of the workshop and may be in Washington, DC office monitoring the workshop through webinar and available by phone and e-mail. EPA staff in attendance at the public meeting and stakeholder workshop may also provide technical direction to contractor staff as needed on the day of the workshop only. EPA staff anticipated to be present are:

- Gwen McClung
- Mark Segal
- Carolina Penalva-Arana
- Stephan Cameron

Pre-Public Meeting and Pre-Stakeholder workshop

The contractor shall provide assistance with logistics including:

- a. Publicizing the public meeting
- b. Setting up a website for the public meeting
- c. Coordinating the registration for the public meeting
- d. Identifying and coordinate with meeting Facilitators. Facilitators should have technical understanding of the subject matter covered by the meeting.
- e. Preparation of packets for stakeholder workshop
- f. Revising and finalizing the agenda for the public meeting
- g. Preparing a detailed itinerary of the order of events at the workshop
- h. Publication of all materials to the website (e.g. agenda, draft document, charge questions, etc.)
- i. Room set-up and arranging/providing AV specifications to the auditorium necessary for the public meeting and webcast

Public Meeting – Morning Session

- a. Arrive prior to meeting to coordinate with EPA and ASU to make sure everything is ready to go for the meeting
- b. Provide facilitator(s) to help guide the meeting through the agenda and keep it on track
- c. Greeting, staffing the registration table, troubleshooting during the meeting
 - a. Distributing meeting materials to registrants
- d. Provide note takers for the meeting

Stakeholder Workshop – Afternoon Session

- a. Hand-out package materials (as needed)
- b. Provide one Facilitator (as needed)
- c. Provide two Note takers (as needed)

Task 3. Post Public Meeting Support and Report Preparation

The contractor shall prepare a final attendee list. The contractor shall prepare a draft summary report of the public meeting. The contractor will receive and incorporate comments to prepare a final report on the meeting. At the end of the docket comment period, the contractor shall prepare a draft comment summary report, which will include all comments received in an appendix as well summarize the main points of each comment.

5.0 DELIVERABLES:

Task	Description	Due Date
1	Kick-off meeting with EPA	Within 5 days after receipt of the work assignment
	Workplan	15 days after receipt of work assignment
	Weekly Progress Summaries	Each Friday, COB during the period of performance
2	Pre-Meeting Support as described in Task 2 above	October 21, 2016
	Meeting and Workshop Support as described in Task 2 above	October 27, 2016
3	Final Attendee List	November 14, 2016
	Draft Meeting Report	November 14, 2016
	Final Report	November 28, 2016
4	Draft Comment Summary Report	December 9, 2016
	Final Comment Summary Report	December 22, 2016

6.0 OTHER:

A Quality Assurance Plan is not required; the Contractor will not be working with environmental data. Confidential Business Information (CBI) does not apply. This Work Assignment relate to Task 7 of the Contract Statement of Work: Provide General Outreach and Presentation Support

7.0 REFERENCES:

Full Text of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

www.epa.gov/assessing-and-managing-chemicals-under-tsca/full-text-frank-r-lautenberg-chemical-safety-21st
Accessed 08-18-2016.

Annex 1: Draft Agenda for Public Meeting

Time	Event	Duration	Person
7:00-8:00 am	Registration	1 hr	?
8:00-8:05 am	Welcome	5 min	?
8:05-8:20 am	Keynote Speaker	15 min	TBD (someone from RAD management)
8:20-8:40 am	Presentation #1: EPA's Risk Assessment Process	20 min	Carolina?
8:40-9:10 am	Comments/Discussion on Presentation #1 (possibly charge questions)	30 min	All
9:10-9:30 am	Presentation #2: Overview of Algae Guidance Document	20 min	Gwen?
9:30-10:00 am	Comments/Discussion on Presentation #2 (possibly charge questions)	30 min	All
10:00-10:15 am	BREAK	15 min	--
10:15-11:50 am	Continue to hear Comments on Algae Guidance document based on charge questions	1 hr 35 min	All
11:50 am-Noon	Closing Remarks	10 min	?
Noon	Adjourn		--

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-10				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name New Chemical Program Support				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2016 To 06/12/2018				
Comments: Initiating a work assignment on EPW16017. The contractor shall provide a work plan within 30 days of receipt of this work assignment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2018				0						
This Action:				0						
				0						
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name Monica Miller <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:				
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:				
Other Agency Official Name Jacqueline Sayles <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-4826 FAX Number:				
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-10				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2017 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name New Chemical Support				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2016 To 06/12/2018				
Comments: Amending work assignment to add additional Sub Task 7, 8, and 9. The contractor shall provide a work plan within 30 days of receipt of this amendment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2017 To 06/12/2018										
This Action: 										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Monica Miller <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:			
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Keith Westry <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:			

Contract Number: EP-W-16017

Work Assignment Number: 1-10

Title: New Chemical Program Support

Purpose:

This work assignment will provide support the New Chemical Program (NCP) in processing of Pre Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled New Chemicals Program Support, is being developed to provide EPA with support to expedite the processing of the Pre Manufacturer Notice (PMN) to reduce the backlog brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will reduce processing times for tracking case status, for developing Letters and Consent Orders, and for writing Significant New Use Rules (SNURs). Completion of all of these activities and their implementation by the NCP should be possible within 3-4 months after issuance of new work assignments under existing contract vehicles.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNURs) before manufacturing can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards and exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which require manufacturers/importers to alert EPA of any new uses of the new chemical substance.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and

the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Document/Data Entry

Complete scanning and entering into PMN Gold all Consent Orders (sanitized and CBI), all CCD Briefing Papers and other CCD-generated documents. All documents scanned into PMN Gold soon will be migrated into phase 1 Enterprise Management System (EMS) by the Information Management Division (IMD).

Subtask 4. Document Sanitization

Sanitize documents by removing Confidential Business Information CBI from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

Subtask 5. Tracking Support

Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD. PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

Subtask 6. Consent Order and SNUR Development

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.

After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none">• Initial QAPP• Revised QAPP(s)	<ul style="list-style-type: none">• 10 days after WA begins• Prior to work on environmental data activities
Subtask 3.	Document/Data Entry	At WAM's Request.
Subtask 4.	Document Sanitization	At WAM's Request.
Subtask 5.	Tracking Support	At WAM's Request.

Subtask 6.	Consent Order and SNUR Development	At WAM's Request.
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- **EPA will approve the work plan within 30 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through - June 12, 2018.

V. Level of Effort:

The estimated level of effort for this work assignment is 1,180 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative

Monica Miller
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Alternate Contracting Officer Representative

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Contract Number: EP-W-16017

Work Assignment Number: 1-10 Amendment.

Title: New Chemical Program Support

Purpose:

This work assignment will provide support the New Chemical Program (NCP) in processing of Pre Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment. This amendment adds Subtasks 7. Pre Notice Communication, 8. Ad Hoc Committee and 9. Miscellaneous Administrative Support. There is no change for Subtasks 1-6.

I. Background:

This work assignment, entitled New Chemicals Program Support, is being developed to provide EPA with support to expedite the processing of the Pre Manufacturer Notice (PMN) to reduce the backlog and implement new requirements brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will reduce processing times for tracking case status, for developing Letters and Consent Orders, and for writing Significant New Use Rules (SNURs). and will provide administrative assistance needed to implement new or enhanced program activities being implemented as a result of the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards and exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which require manufacturers/importers to alert EPA of any new uses of the new chemical substance. Pre Notice Communication is an effort for Program staff to work with potential PMN submitters to provide information and guidance to improve the quality and contents of a PMN which should help make the review process more efficient.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality

aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Document/Data Entry

Complete scanning and entering into PMN Gold all Consent Orders (sanitized and CBI), all CCD Briefing Papers and other CCD-generated documents. All documents scanned into PMN Gold soon will be migrated into phase 1 Enterprise Management System (EMS) by the Information Management Division (IMD).

Subtask 4. Document Sanitization

Sanitize documents by removing Confidential Business Information CBI from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

Subtask 5. Tracking Support

Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD. PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

Subtask 6. Consent Order and SNUR Development

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.

After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

Subtask 7. Pre Notice Communication Program (New Task)

Provide support in Scanning Historical files containing information and notes on approximately 4000 Pre Notice Communications including correspondence and meetings. The files will be used to modify and populate an existing database with existing and new metadata requested by the WAM.

Subtask 8. New Chemicals Ad Hoc Committee Support (New Task)

Provide support to the Ad Hoc committee on New Chemicals by drafting decision documents using a template and populating with data and information from Chemical Control Division briefing papers and Risk Assessment Division documents supporting review of New Chemicals. Attend Ad Hoc New

Chemicals Prep meetings currently being held twice weekly and tracking progress of PMNs thru the Committee process.

Subtask 9. Miscellaneous Administrative Support (New Task)

Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and files, tracking progress of work effort, database creation, population and maintenance and completing information requests.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none">• Initial QAPP• Revised QAPP(s)	<ul style="list-style-type: none">• 10 days after WA begins• Prior to work on environmental data activities
Subtask 3.	Document/Data Entry	At WAM's Request.
Subtask 4.	Document Sanitization	At WAM's Request.
Subtask 5.	Tracking Support	At WAM's Request.
Subtask 6.	Consent Order and SNUR Development	At WAM's Request.
Subtask 7.	Pre Notice Communication	At WAM's Request.
Subtask 8.	Ad Hoc Committee	At WAM's Request.
Subtask 9.	Miscellaneous Administrative Support	At WAM's Request.

- **EPA will approve the work plan within 30 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature.

V. Level of Effort:

The estimated level of effort for this work assignment is 1,280 professional hours. This modification increases the level of effort by 870 hours to a total of 2150 hours.

VI. EPA Contacts:

Primary Contracting Officer Representative

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Alternate Contracting Officer Representative

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Buckley.christopher@Epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-11				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name New Chemical Support for SNURS				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments: Initiating a Work Assignment on EPW16017. The contractor shall provide a work plan within 30 days of receipt of the work assignment										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee:						LOE: 0				
06/13/2016 To 06/12/2018										
This Action:						0				
Total:						0				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:						Cost/Fee LOE:				
Cumulative Approved:						Cost/Fee LOE:				
Work Assignment Manager Name Martha Miller <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 202-564-0295				
						FAX Number:				
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 202-564-3121				
						FAX Number:				
Other Agency Official Name Jacqueline Sayles <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 919-541-4826				
						FAX Number:				
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 202-564-4353				
						FAX Number:				

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-11				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2017 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW Technical Support for Significant New Use Rules, C					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance From 06/13/2017 To 06/12/2018					
Comments: Amended to update statement of work for Battelle WA 1-11 Contractor shall provide workplan 30 days after receipt of work assignment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2017 To 06/12/2018										
This Action: 										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Martha Miller <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-0295 FAX Number:			
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

Contract Number: EP-W-16017

Work Assignment Number: 1-11

Title: New Chemical Program Support for Significant New Use Rules, Consent Orders, and Other New Chemical Regulatory Activities

Purpose:

This work assignment will provide support the New Chemical Program (NCP) in collecting, formatting and data entry into the Chemical Control Divisions Consent Order/SNUR database. No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled New Chemical Program Support for Significant New Use Rules, Consent Orders, and Other New Chemical Regulatory Activities, is being developed to provide EPA with support for making TSCA regulatory actions more readily available to other government agencies, as well as the public.

The Premanufacture Notice (PMN) program is mandated by Section 5 of the Toxic Substances Control Act (TSCA). EPA's New Chemicals Program (NCP), which is part of the Office of Pollution Prevention and Toxics (OPPT), is responsible for coordinating the review process of Premanufacture Notice (PMN) submissions and identifying new substances that require regulatory action. The New Chemicals Management Branch (NCMB) in the Chemical Control Division (CCD) of OPPT is responsible for the risk management of new chemicals.

During the Agency's review period, EPA must determine whether the chemical should be regulated because it may present an unreasonable risk to human health or the environment. One method of regulation is for the EPA to enter into a Consent Order with the Company (under Section 5(e) of TSCA), which allows production of the chemical to proceed under specific restrictions. Under the Expedited Follow-up Rule effective October 10, 1989, when a 5(e) Consent Order is issued for a new chemical substance, EPA is obligated to issue a Significant New Use Rule (SNUR) within a limited period of time. Other deadlines exist for previously issued 5(e) Orders and for new chemical substances that pass through new chemical review but are identified as non-5(e) SNUR candidates. The purpose of the Significant New Use Rule (SNUR) is to extend regulation of new chemicals beyond the PMN submitter.

CCD will utilize information contained in the CCD Consent Order/SNUR database to create an MS Access Database to populate the Chemview system for generation of Chemview Templates. All information uploaded into the Chemview system would not contain Confidential Business Information (CBI). Chemview will be the program to make TSCA regulatory actions more readily available to other government agencies, as well as the public.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Collection of Supporting Documents

The contractor shall initiate collection of supporting and source documents including Federal Register Notices and TSCA Section 5(e) Consent Orders for PMNs identified by the WAM in written technical direction. The Contractor shall utilize all available resources, including the Documentum and CIS databases - electronic version of the files from the Confidential Business Information Center (CBIC), PMN Gold Workflow System, the CBI LAN, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI, however, they are located in a CBI environment. In those instances, when the documents are not located in a CBI environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Work Assignment Manager (WAM) shall provide guidance on naming and storage of the collected documents. The Contractor shall notify the Work Assignment Manager (WAM) of any files which are missing.

Subtask 4. Formatting of Supporting Documents

The contractor shall provide technical assistance to the WAM in formatting of supporting documents as Adobe pdfs. The WAM shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the Chemview system. Formatted pdf documents must be text searchable to accommodate the functionality within the Chemview system.

The contractor shall track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For the signed 5(e) Consent Orders, the contractor shall notify the WAM of any delays in completion of the reports, and to obtain any sanitized orders that are not available. As the EPA contact, the WAM is responsible for certifying that all formatted documents are suitable for transmission to the Chemview system.

Subtask 5. CCD Consent Order/SNUR database

The contractor shall use the collected 5(e) Consent Orders and Federal Register Notices for all SNURs to review and populate tables within the CCD Consent Order/SNUR database. All identified chemicals shall be entered into the system using the guidance documents provided by the WAM. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and

QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the WAM. Using the information contained in the database, the contractor shall create MS Access database files for upload into the Chemview system. The Chemview workgroup will review all data and uploaded support documents prior to final approval and publication in the public Chemview database.

5.1 Chemical Identity Verification

The contractor shall review and capture information from the sanitized documents to populate the chemical identities included in either the 5(e) Consent Orders or SNUR. This identity will include the Non-Confidential Name, as well as any public CAS/Accession Number where available. The WAM shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide what information is available, and the EPA WAM will coordinate verification of the suitable names.

5.2 Database Data Entry

The contractor shall use the non-confidential documents collected, and guidance provided by the WAM to enter data into the CCD Consent Order/SNUR database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be found for each data field. The contractor shall pose any questions to the WAM as soon as possible to allow additional guidance to be provided.

In addition, the database contains a "Comment" field designed for the contractor to enter any comments, observations, or notes they wish the WAM to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the WAM.

5.3 Report Generation

The contractor shall assist the EPA WAM in creation of various reports using the export functions of the CCD Consent Order/SNUR database. The contractor shall coordinate with the WAM the procedures for generation of the reports and any formatting requirements that may be needed.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none"> • Initial QAPP • Revised QAPP(s) 	<ul style="list-style-type: none"> • 10 days after WA begins • Prior to work on environmental data activities
Subtask 3.	Collection of Supporting Documents (Status Update to include including identification of missing documents.)	At WAM's Request.

Subtask 4.	Formatting of Supporting Documents (Monthly status update to include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for WAM review.)	At WAM's Request.
Subtask 5.	CCD Consent Order/SNUR database and monthly (Monthly status update to include the progress of chemical identity verification, including notation of changes in identities and any updates made to the CCD Consent Order/SNUR database; progress on the completion of the data entry; and report generation.)	At WAM's Request.

- **EPA will approve the work plan within 45 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

V. Level of Effort:

The estimated level of effort for this work assignment is 1,600 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative

Monica Miller
WJC East Building, Rm 4133-D, MC 7405M
1200 Penn. Ave, NW, Washington, DC 20460
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miller.monica@epa.gov

Alternate Contracting Officer Representative

Christopher Buckley
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1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-4817
Buckley.christopher@Epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-12				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name CBI LAN Reviews				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments: Initiate work assignment. The Contractor shall provide a work plan within 30 days of receipt of the work assignment										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2018										
This Action:						0				
Total:						0				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name Skyler Dobert						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-564-3159				
						FAX Number:				
Project Officer Name Tyrone Thomas						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-564-3121				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number:				
						FAX Number:				
Contracting Official Name Jody Gosnell						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-564-4353				
						FAX Number:				

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-13				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2020 Base Option Period Number 1			Title of Work Assignment/SF Site Name OSCP EDSP Support				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments: Initiating a work assignment on EP-W-16-017. The contractor shall provide a work plan within 30 days of receipt of this work assignment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2020										
This Action:						0				
Total:						0				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Sharlene Matten <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-0130 FAX Number:			
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name Keith Westry <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:			
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-13				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2018 To 06/12/2019 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name OSCP EDSP Rec Man, Data Analy				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments: The purpose of this amendment is to add 600 work hours to work assignment WA 1-13. The focus of the additional hours will be to complete work under Subtask 3, Records Management and Subtask 5, Meeting Support. Subtask 6 (Special Projects) has been changed to an optional subtask. Finally, the alternate										
<input type="checkbox"/> Superfund						Accounting and Appropriations Data				<input checked="" type="checkbox"/> Non-Superfund
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
06/13/2018 To 06/12/2019										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name Sharlene Matten <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div>							Branch/Mail Code:			
							Phone Number: 202-564-0130			
							FAX Number:			
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div>							Branch/Mail Code:			
							Phone Number: 202-564-3121			
							FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name Keith Westry <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div>							Branch/Mail Code:			
							Phone Number: 202-564-9863			
							FAX Number:			

Contract Number: EP-W-16-017
Addendum to Work Assignment Number 1-13

Title: Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects

Purpose:

The purpose of this addendum is to add 600 work hours to work assignment WA 1-13. The focus of the additional hours will be to complete work under Subtask 3, Records Management and Subtask 5, Meeting Support. Subtask 6 (Special Projects) has been changed to an optional subtask. Finally, the alternate Work Assignment COR has been changed from Kristan Markey to Scott Lynn.

This work assignment, Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects, shall provide support to the Endocrine Disruptor Screening Program (EDSP). No work performed under previous task orders or work assignments will be duplicated under Work Assignment 1-13, EP-W-16-017.

I. Background

This work assignment, Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects, will provide support for four (4) specific areas:

1. Records management
2. Data analysis and statistical support
3. Meeting support
4. Special projects.

The Endocrine Disruptor Screening Program (EDSP) was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results, allowing for greater coverage of the endocrine system.

Work Assignment 1-13 of EPA Contract No. EP-W-16-017 will continue records management work conducted by Battelle on Task Order 19 of EPA Contract No. EP-W-11-063 (Subtask 3), and statistical support and data

analysis of the studies conducted by Battelle on Task Orders 14, 17, and 19 of EPA Contract No. EP-W-11-063 and conducted by RTI on Task Orders 12 and 13 of EPA Contract No. EP-W-11-065 (Subtask 4). No work performed under these earlier task orders will be duplicated under Work Assignment 1-13. Work Assignment 1-13 also includes support for meetings (Subtask 5) and special projects (Subtask 6).

II. Statement of Work

Subtask 1. Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
2. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.
3. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files. All Deliverables for WA 1-13 are the property of EPA.
4. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 4 and 6 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Records Management

The contract shall provide EPA with technical assistance on activities related to records management.

1. The contractor shall assist EPA in managing records, in all media, according to the disposition instructions in EPA record management schedules, including but not limited to:
 - EPA Record Schedule 1035 - Environmental Records
 - EPA Record Schedule 1004 - Acquisitions and Contracts
 - EPA Records Schedule 1024 - Federal Advisory Committee Records
2. The contractor shall provide support for:
 - Organizing and indexing records
 - Packing and labeling boxes containing records for transfer to a Federal Records Center or as a direct offer to the National Archives and Records Administration.
 - Preparing individual box lists

- Preparing destruction lists for records that will be destroyed and destroying them
 - E-record management
3. The contractor shall provide the WA COR with:
 - Draft and final indices of records (in all media)
 - Draft and final box lists
 - Organized, packed, and labelled records boxes for transfer to FRC or NARA
 - Draft and final records destruction forms.
 4. The contractor shall conduct work with paper records at EPA William Jefferson Clinton East, Office of Science and Coordination Policy, Washington D.C., unless otherwise dictated by the EPA WA COR.
 5. The contractor shall have one technical meeting per week with Battelle and/or its subcontractor.

Subtask 4: Statistical Support and Data Analysis

The contractor shall provide EPA with technical assistance in data and biostatistical analysis, particularly data from toxicological/toxicokinetic studies. EPA may order work that requires a short turn-around time. Battelle shall use, to the extent possible, open source tools, e.g., programs in R.

The contractor shall provide support for:

1. Data and statistical analysis, e.g., compiling and evaluating in vitro and in vivo data from multiple sources, preparing or revising reports, statistical support and data analysis for publication, preparing data evaluation records using EPA study profile templates for the EDSP, etc.;
2. Data management related to specific data/statistical analyses.

The contractor shall prepare draft and final analyses/reports/DERs, etc. per the WA COR's instructions.

Examples include:

1. Development of EPA Data Evaluation Records from EPA-sponsored laboratory studies including supporting statistical analysis, as needed.
2. Statistical analysis of EPA data either for an individual study or multiple studies
3. Meta-analysis of collected data from EPA in vitro/in vivo studies
4. RSCABS of EPA histopathology data
5. Data and statistical analysis of EPA toxicokinetics data
6. Cross-species analyses
7. Analysis of in vitro toxicokinetics data in trout, rat, and human.

Subtask 5: Meeting Support

The contractor shall provide EPA with meeting support, e.g., EPA meetings/workshops which are open to specific invitees or open to public. The primary focus of this subtask will be on providing support for note-taking, transcription, and summary reports of EPA meetings.

For example, Battelle may also assist EPA in the following areas:

- Logistical support, e.g., managing a webinar, managing audio/visual equipment
- Meeting invitations and tracking responses
- Development of meeting materials

Subtask 6 (Optional): Special Projects

The contractor shall provide EPA with assistance on activities including, but not limited to, conducting technical studies on chemicals that are from the EDSP Universe and the TSCA work plan.

Studies may include the evaluation of new and emerging technologies to measure, detect, or reduce exposure to toxic substances.

Example - Investigation of volatility and solubility. EPA has designed a Cell Culture Exposure System for in vitro testing of volatile chemicals. The contractor shall build the device to test volatile chemicals from the EDSP Universe and the TSCA Work Plan.

The contractor shall prepare draft and final analyses/reports etc. per the WA COR's instructions.

III. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

SubtaskNo.	Deliverable Title/Brief Description	Original Due Date	Revised Due Date	Percent Complete (as of 5/1/2018)
1	Technical and Financial Work Plan (MAY NEED TO ADD HOURS)	10/25/17	11/20/17	100
2	Draft QAPP	10/10/17	11/13/17	100
2	Final QAPP	--	1/15/18	100
3	Records Management deliverables (NEED TO ADD HOURS)	TBD in technical direction	Weekly updates starting 12/1/17	75
4	Data Analysis and Statistical Support deliverables	TBD in technical direction	1. 2/21/18	33
5	Meeting Support (NEED TO ADD HOURS)	TBD in technical direction	As required in technical directive	50
6	Special Projects (Optional) [No work requested during this option period ending June 12, 2018.]	TBD in technical direction	As required in technical directive	0

- 1. EPA will approve the work plan within 30 days.**
- 2. A Quality Assurance Project Plan (QAPP) is required (Subtasks 4 and 6).** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- 3. CBI does not apply.**
- 4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently**

governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

IV. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

- V. **Amended Estimated Level of Effort:** Additional 600 professional hours. Total estimated level of effort 1700 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative

Sharlene R. Matten, Ph.D.
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Alternate Contracting Officer Representative

Scott Lynn
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1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-2631
lynn.scott@epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-14				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2018 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name OSCP Alternative Testing				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments: Initiating a work assignment on EP-W-16-017. The contractor shall provide a work plan within 30 days of receipt of this work assignment.										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2016 To 06/12/2018										
This Action: 										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Kristan Markey <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202 564 8716 FAX Number:			
Project Officer Name Tyrone Thomas <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Jody Gosnell <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

Contract Number: EP-W-16-017

Work Assignment Number: 1-14

Title: EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support

Purpose:

This work assignment, EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPA's Office of Chemical Safety & Pollution Prevention (OCSPP) including the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 1-14, EP-W-16-017.

I. Background

This work assignment will provide technical support in three specific areas:

1. Support the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act via development of an inventory of testing requests and existing data and analysis of this inventory;
2. Support EDSP linear and pathway-based systematic literature reviews to support the performance-based validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies
3. Support collecting, prioritizing, and analyzing in vitro and in vivo data for display on the EPA Comptox dashboard via systematic review (SR) and high-throughput assays (in vitro only)

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system.

I. Statement of Work

Subtask 1. Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
2. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.
3. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.
4. All Deliverables for WA 1-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).
5. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3, 4, and 5 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy

1. **Data Processing on Testing Requests and Requirements.** The contractor shall convert data from TSCA Section 4 & 5 regulatory letters and databases and TSCA Sections 4, 5, and 8 hazard and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
2. **Data Processing on Existing Chemical Data.** The contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
3. **Data Analysis.** The contractor shall determine which tests are most commonly requested and determine

trends of data requests based on chemical classes and other variables. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies.

Subtask 4. EDSP linear and pathway-based systematic literature reviews

1. **Continuation of EDSP Linear Systematic Literature Reviews.** The Contractor shall continue to support EPA with scientific expertise to perform title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on the Fish Short-Term Reproduction Assay (FSTRA), and Male and Female Pubertal Assays initiated under EPW-11-063, Task Order 11; and the Amphibian Metamorphosis Assay and cross-species Fish Short Term Reproduction Assay initiated under EPW-11-063, Task Order 16.
2. **EDSP pathway-based systematic literature reviews.** The Contractor shall assist EPA with developing and implementing approaches for pathway-based systematic literature reviews such as the steroidogenesis and thyroid-related pathways and molecular-initiating events (MIEs). Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design and workflow management.
3. **Data management of EDSP Systematic Reviews.** The Contractor shall support the development and implementation EDSP and OECD Harmonized Templates, reviewer workflows, and reference management in systematic review tools selected by EPA.
4. **Analysis of EDSP Systematic Reviews.** The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), toxicological, and textual analysis (such as text mining and natural language processing analysis) of EDSP systematic reviews.

Subtask 5: Development and Prioritization of the EDSP Universe

The Contractor shall support the curation, clustering, and prioritization of chemical substances from the EDSP Universe of Chemicals including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.

II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

Tasks	Deliverables	Due Dates
Subtask 1	Work plan and task management The contractor shall prepare and submit the work plan in accordance with contract requirements.	

Tasks	Deliverables	Due Dates
Subtask 2	Quality Assurance Project Plan (QAPP) 1. Draft QAPP 2. Final QAPP	1. Draft: 10 days after WA begins 2. Prior to work on environmental data activities
Subtask 3	Development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy	At Work Assignment COR's request.
Subtask 4	EDSP linear and pathway-based systematic literature reviews	At Work Assignment COR's request.
Subtask 5	Development and Prioritization of the EDSP Universe	At Work Assignment COR's request.

- 1. EPA will approve the work plan within 30 days.**
- 2. A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- 3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2; otherwise, no CBI is involved.**
- 4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

IV. Estimated Level of Effort: 1,000 professional hours.

V. EPA Contacts:

Primary Contracting Officer Representative

Kristan Markey
WJC East Building, Rm 4106-H, MC 7203
1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-8716
markey.kristan@epa.gov

Alternate Contracting Officer Representative

TBD

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 1-15				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period 06/13/2016 To 06/12/2018 Base Option Period Number 1			Title of Work Assignment/SF Site Name National Fish Tissue Data Repo				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 06/13/2017 To 06/12/2018				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 06/13/2016 To 06/12/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee LOE:										
Cumulative Approved: Cost/Fee LOE:										
Work Assignment Manager Name Samantha Fontenelle							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 202-566-2083			
							FAX Number:			
Project Officer Name Tyrone Thomas							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 202-564-3121			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name Jody Gosnell							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 202-564-4353			
							FAX Number:			

PERFORMANCE WORK STATEMENT
EP-W-16-017
Work Assignment 1-15

TITLE: National Fish Tissue Data Repository

WORK ASSIGNMENT COR (WA-COR): Samantha Fontenelle
Standards & Health Protection Division
US EPA (4305T)
Washington DC 20460
202-566-2083
202-566-0409 FAX

Lisa Larimer (Alternate)
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PERIOD OF PERFORMANCE: Work Assignment issuance through 06/12/2018

I. Background and Scope of Work

Background

The National Listing of Fish Advisories (NLFA) is a national online database of fish advisories and fish tissue contaminant data collected by states, territories and tribes (hereafter states). It was developed in 1992 and includes advisory information for 50 states, District of Columbia, and the U.S. territories of American Samoa and Guam. It also includes fish tissue contaminant data which served as the basis for state-issued advisories for 48 states. Since 2000, the survey of fish advisories has been performed under an approved ICR for the National Listing of Advisories (OMB Control No. 2040-0226).

In 2010, EPA began a significant modernization of the NLFA. Two new mapping interfaces were designed: one for the general public and the other for technical users. The new application includes easy-to-use drop-down search forms with type-ahead functionality and reports search results in map format, table format, or as a downloadable spreadsheet or PDF report. In 2012, the new application was released publicly. The most recent update of the NLFA occurred in December 2013 and included only the state advisory information for 2011. The NLFA application are available at <https://fishadvisoryonline.epa.gov/FishTissue.aspx> and <https://fishadvisoryonline.epa.gov/Advisories.aspx>.

Scope of Work

Under this work assignment, the contractor shall assist EPA with the collection, standardization, and migration of state fish tissue contaminant data.

II. Tasks

Task 1 – Work Plan and Quality Assurance Project Plan (QAPP)

The Contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA. The contractor shall present its technical approach and budget addressing all the tasks in this work assignment.

The Contractor shall develop a Quality Assurance Project Plan (QAPP) to ensure the accuracy and completeness in transcribing and reporting the fish tissue data. The Contractor shall ensure and document that all activities are in accordance with Agency guidance and in compliance with EPA metadata standards. The QAPP shall address the elements in the Modified QAPP Format for Existing Data Projects (Attachment A). The Contractor shall provide all SOPs used for verifying accuracy of data transcription, GIS/georeferencing and other pertinent project-related activities. EPA's guidance on developing QAPPs can be found at www.epa.gov/quality.

The QAPP must be approved by the Contractor's quality assurance/quality control (QA/QC) officer and the EPA/OST QA/QC officers prior to the request for data from the states (Task 4). All deliverables shall include a report describing compliance with the QAPP. The work performed in the performance work statement (PWS) shall conform to the Information Quality Guidelines (IQG) Checklist (Attachment B). The completed checklist shall be submitted with the final deliverables.

Task 2 - Data Management Plan

The Contractor shall assist EPA with addressing any deficiencies in a draft Data Management Plan (DMP). The purpose of the plan is to describe the process for collecting, standardizing, migrating and managing the fish tissue data to ensure consistency. The WACOR shall provide the Contractor with the draft DMP (See Attachment C).

In revising the document, the Contractor shall incorporate the following decisions that were made after the draft DMP was completed:

1. **Years of data to be migrated from the NLFA to STORET/WQX/WQX:** 1998 to 2010.
2. **Tissue types to be included:** fillet, whole body, plug, shellfish and wildlife. Currently, the NLFA does not contain shellfish, wildlife and plug data.
3. **Chemical contaminants to migrate:** All chemical contaminants in the NLFA

Task 3 – NLFA Data Review and Standardization

Data quality issues exist with the state fish tissue contaminant data in the NLFA. The Contractor shall assist EPA with the review of state tissue data and perform, as necessary, data cleanup to address data quality and other issues.

The Contractor shall also conduct a thorough review and comparison of the state fish tissue data

in STORET/WQX to the data in the NLFA. The Contractor shall provide the WACOR with a list of states with fish tissue data in STORET/WQX, number of reported results by year, an assessment of the quality of the data, a report of the results of the comparison of the data in STORET/WQX and NLFA.

The contractor shall assist with standardizing chemical analyte name, species taxa, etc.; acquiring missing or additional data parameters (e.g., method detection limits, analytical methods, latitude/longitude, etc.), and addressing other data related issues. The data review and standardization shall be conducted to ensure that data migrated to STORET/WQX is of high quality and can be used for human health risk assessment purposes.

The Contractor shall work closely with EPA and each state to ensure that their data are correctly standardized and QAed before they are migrated to STORET/WQX. For estimating purposes, the Contractor shall assume data from 8 states will be reviewed and standardized.

Task 4 – Data Collection

For some states, data elements and years of the data may be missing (e.g., lat/long, method detection limits, etc.) or data may be inaccurate because changes were made after the data were submitted to EPA. The Contractor shall support EPA in obtaining missing or accurate fish tissue data from states for 1998 through 2010. This task will require the Contractor work closely with the states.

The Contractor shall also work with the EPA STORET/WQX Team to make any changes necessary to the existing USEPA WQX Web Fish Tissue Template in order for states to provide data not currently included in the template as well as upload their data into STORET/WQX seamlessly using the WQX XML data flow or WQX web tool.

Task 5 – Data Migration

The Contractor shall add the standardized tissue data into the STORET/WQX and notify each state when its data have been migrated into STORET/WQX. For cost estimating purposes, the Contractor shall assume 50,000 fish tissue sample results shall be added to STORET/WQX.

III. Deliverables

The Contractor shall prepare draft deliverable(s) for review by the EPA WACOR in accordance with the deliverable schedule in section IV or by technical direction (TD). In preparing final written deliverables the Contractor shall incorporate written comments from the EPA WACOR and submit the final deliverables in accordance with the deliverable schedule in section IV or TD. The EPA WACOR will review and approve all final deliverables.

Draft and final deliverables including reports, data, databases and maps shall be provided to the WACOR electronically. Electronic files shall be provided in PDF and/or in the original software (Excel, Word). The Contractor shall use Microsoft Office and Adobe Acrobat software for developing all electronic copies of deliverables associated with the work assignment.

IV. Schedule of Deliverables

Task	Deliverable	Schedule
1	Work Plan	Per contract requirements
1	Draft QAPP	Within 20 business days of approval of the work assignment
1	Revised QAPP	Within 5 business days of receipt of EPA's comments on the draft QAPP
1	Final QAPP	One month before work assignment completion
1	Information Quality Guidelines	Within 10 business days of completion of the work assignment
2	Revised DMP	Within 20 business days of approval of the work assignment
2	Final DMP	Within 7 business days of receipt of EPA's comments on the revised DMP
3	List of states with fish tissue data in STORET/WQX	As requested by the WACOR
3	Biweekly updates on status of standardization of state data	As requested by the WACOR
4	Status updates on data collection efforts	As requested by the WACOR
4	List of recommended changes to the Fish Tissue Template	As requested by the WACOR
5	Status update on data migration	Within 5 business days of migration of state data

IV. Reporting:

The Contractor shall include all progress for this WA in the monthly report prepared for this contract. The monthly report shall also include any QA issues encountered and recommendations for resolution. Financial reports shall also be completed as specified in the contract. Financial reports shall also be completed as specified in the contract. The Contractor shall maintain a file of all documentation, including raw data, calculations, assumptions, telephone contacts, and sources of information.

During the period of performance of this work, the contractor shall immediately inform the EPA WACOR by email of any problems that may impede performance along with any corrective actions needed to solve the problem.

V. Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

VI. Travel:

No travel is anticipated under this work assignment. However, any travel chargeable to this work assignment shall be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46, and must be approved by the EPA Project Officer prior to travel taking place.

VII. Printing:

All copying and printing shall be accomplished within the limitations of the printing clause of the contract.

VIII. Meetings, Conferences, Training Events, Award Ceremonies, and Receptions:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, including the form 5170 for all meetings costing more than \$20,000, shall be obtained by the EPA CL COR as needed and provided to the Contracting Officer Work under conference-related activities and expenses shall not occur until this approval is obtained and provided by the EPA CL COR.

ATTACHMENT A
Modified QAPP Format for Existing Data Projects

ATTACHMENT B

Office of Water Information Quality Guidelines Checklist for Non-*Influential Information*

**Office of Water
Information Quality Guidelines Checklist for
Non-Influential Information**

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
 - ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
 - ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
 - ☐ Utility: the information is useful to the intended users.
- ☐ Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.

Division Director's Signature & Date

IQG Officer for OW Signature & Date

ATTACHMENT C
DRAFT DATA MANAGEMENT